Exhibit A

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF PUERTO RICO

THE GOVERNMENT OF PUERTO RICO,

Plaintiff,

v.

CAREMARKPCS HEALTH, L.L.C.; CAREMARK PUERTO RICO L.L.C.; EXPRESS SCRIPTS, INC.; and OPTUMRX INC.,

Defendants.

Civil No. 23-1127 (JAG)

PLAINTIFF GOVERNMENT OF PUERTO RICO'S
SECOND AMENDED COMPLAINT

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TO THE HONORABLE COURT:

NOW COMES Plaintiff The Government of Puerto Rico ("Puerto Rico" or the "Government"), through its undersigned counsel, and respectfully brings this action against Defendants CaremarkPCS Health, L.L.C. and Caremark Puerto Rico LLC (collectively, "CVS Caremark"); Express Scripts, Inc. ("Express Scripts"); and OptumRx Inc. ("OptumRx") (collectively, "Defendants")[1] pursuant to Puerto Rico's Fair Competition Act, 10 L.P.R.A. § 259. In support of its claims, the Government alleges, states, and prays as follows:

INTRODUCTION

1. Prescription drug pricing in the United States is complex and opaque, allowing Defendants—the three largest pharmacy benefit managers ("PBMs") in the country—to siphon increasing amounts of money from the pharmaceutical supply chain through an unfair and deceptive scheme that masks Defendants' negative impact on the market while increasing consumers' out-of-pocket costs, controlling independent pharmacies, and maximizing rebates for Defendants' own financial gain at the expense of consumers and the Government. These consumers are patients in need of medical treatment, including many elderly consumers, who often are more vulnerable than the general population, both physically and financially.

2. The Government brings this Complaint to address Defendants' violations of Puerto Rico law that significantly contribute to these high prices, and to ensure that consumers (*i.e.*, patients in need of medical care) can access affordable, safe, and effective drugs. As laid out specifically below, Defendants have engaged in deceptive acts and practices in violation of 10 L.P.R.A. § 259 (Count One); engaged in unfair acts and practices in violation of 10 L.P.R.A. §

[1] The Government has agreed not to include Manufacturer Defendants in the SAC but reserves the right to seek leave to amend to add the Manufacturer Defendants if appropriate.

259 (Count Two); damaged the Government as a result of Defendants' unfair and deceptive acts and practices in violation of 10 L.P.R.A. § 268(b) (Count Three); and engaged in unfair methods of competition in violation of 10 L.P.R.A. § 259 that negatively impacted competition in the prescription drug and pharmacy markets, which have harmed consumers (Count Four).

3. All allegations set forth herein regarding Defendants' unfair and deceptive acts and practices with respect to consumers in Puerto Rico also establish and constitute unfair and deceptive acts and practices against the Government itself, in its capacity as a third-party payer seeking to provide meaningful, cost-effective drug benefits to Government employees and retirees. Both the Government and the consumers described herein have suffered substantial injury and, in the case of the Government, damages, as a result of Defendants' unfair and deceptive acts and practices.

4. Defendants contract with health benefit plans based in and outside of Puerto Rico and with pharmacies to provide services to Puerto Rico consumers. They refer to consumers as their "members" and represent that their primary role is to serve members.

5. Defendants make numerous deceptive representations, directly and indirectly, to consumers that Defendants act to serve consumers by lowering drug prices and ensuring consumers' access to safe and effective drug treatments. Yet, over time, Defendants have developed a business model that does the opposite.

6. Defendants have promised to apply objective medical science and the leverage of large-scale purchasing to select the safest and most effective drugs for consumers and bring down their prices. Instead, they have capitalized on their role as middlemen between drug manufacturers, pharmacies, health insurance plans, and consumers to siphon increasing revenue to themselves, drive up prices to consumers, and protect their own role and profits by shrouding them in secrecy

and misleading marketing. Defendants' drug "formularies" (lists of covered drugs, as explained in more detail below) are now so restrictive that they block consumers' access to nearly 40% of drugs on the market—forcing consumers to shift their prescription medications around Defendants' changing formulary decisions instead of their own medical needs.[2]

7. Over the last decade, there has been a fundamental shift in drug prices and payments. Manufacturer payments to Defendants and other PBMs now constitute 40% or more of brand-name prescription drug costs.[3] In 2013, the manufacturer Sanofi offered rebates for insulin products between 2% and 4% for preferential treatment on CVS Caremark's formulary. By contrast, in 2018, Sanofi's rebates for insulin products were as high as 56% for preferred formulary placement.[4]

8. The Government, as a third-party payer, has also paid increased costs for drugs as a result of Defendants' unfair and deceptive acts and practices.

9. Defendants engage in unfair methods of competition that negatively affect competition in the prescription drug market by giving preferential treatment to drugs with the highest rebates, even when there are multiple, equally effective drugs in a therapeutic class. For example, in order to profit from rebates and other fees, Defendants give preferential status to high cost, brand-name insulin products over lower cost insulin biologics that the U.S. Food and Drug

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[2] Geoffrey Joyce et al., *Medicare Part D Plans Greatly Increased Utilization Restrictions On Prescription Drugs, 2011–20*, 43 Pharm & Med. Tech. 391, 396–97 (2024), https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2023.00999.

[3] Emery P. Weinstein & Kevin Schulman, *Exploring Payments in the U.S. Pharmaceutical Market 2011–2019: Update on Pharmacy Benefit Manager Impact*, 227 Am. Heart J. 107, 108 (2020), https://doi.org/10.1016/j.ahj.2020.06.017.

[4] Staff of U.S. Senate Comm. on Finance, 117th Cong., *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* (Jan. 14, 2021) at 82, https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf (hereinafter "Senate Finance Committee Insulin Report").

Administration ("FDA") approved to be *fully interchangeable* with the brand-name products. As will be discussed, Defendants' business model has many inherent conflicts of interests that go unchecked due to the lack of transparency in the marketplace. This negatively impacts consumers paying inflated cost-share payments tied to a drug's "list price," also known as its "Wholesale Acquisition Cost" or "WAC" (*e.g.*, uninsured consumers and insured consumers with coinsurance or high-deductible plans).[5]

10. Defendants also engage in unfair methods of competition that harm independent pharmacies—including independent pharmacies in Puerto Rico—while providing an advantage to their own pharmacies and negatively affecting competition and consumers. Defendants use their dominant market power (explained below) to force their unaffiliated pharmacies to accept unfair contractual terms. This includes reimbursing independent pharmacies near or below acquisition costs for dispensing lower-profit prescriptions and steering prescriptions for higher-profit drugs to Defendants' own affiliated pharmacies. These practices unfairly lessen independent pharmacies' ability to compete with big, chain pharmacies, ultimately raise prices for consumers, and deny consumers their choice of pharmacy.

PARTIES

Plaintiff Government of Puerto Rico

11. Plaintiff, Government of Puerto Rico, by and through the Secretary of Justice of Puerto Rico, Domingo Emanuelli Hernández, brings this action to protect the interests of Puerto Rico and its residents. The Secretary of Justice brings this action pursuant to his statutory authority under 10 L.P.R.A. § 269 to enforce the Puerto Rico laws prohibiting unfair methods of competition and unfair or deceptive acts or practices in trade or commerce.

[5] Even patients with more modest deductibles are still negatively impacted by these inflated prices until they have exhausted their deductibles.

12. In this action, the Government does not make any claims regarding or seek recovery for any acts or practices relating to any federal health insurance and/or health benefits program, including but not limited to Medicaid, Medicare, TRICARE, and/or Federal Health Benefits Act ("FEHBA") plans. All claims asserted herein relate exclusively to non-federal health insurance and/or health benefits programs.

13. Moreover, the Government's claims are not limited to insulin or other diabetes medications, but rather are based on larger unfair and deceptive acts and practices of which insulin is one example. These unfair and deceptive acts and practices, described in detail below, violate 10 L.P.R.A. § 259, increase prices, reduce access to brand-name prescription drugs for Puerto Rico consumers, and harm competition in the prescription drug and pharmacy markets to the detriment of consumers.

Defendants CaremarkPCS Health, L.L.C. and Caremark Puerto Rico L.L.C.

14. Defendant CaremarkPCS Health, L.L.C. (operating as CVS Caremark) is a Delaware limited liability company that maintains its principal place of business in Rhode Island. At all times relevant to this Complaint, CVS Caremark provided pharmacy benefit management services in Puerto Rico.

15. CaremarkPCS Health, L.L.C.'s affiliate in Puerto Rico is Caremark Puerto Rico L.L.C., a Puerto Rico limited liability company.

16. At all relevant times, CaremarkPCS Health, L.L.C. and Caremark Puerto Rico L.L.C. (collectively, "CVS Caremark") had agreements with various pharmaceutical manufacturers related to payments for preferred placement on CVS Caremark's standard formularies.

17. CVS Caremark has the largest PBM market share based on total prescription claims managed, representing approximately 33% of the national market.[6]

Defendant Express Scripts, Inc.

18. Defendant Express Scripts, Inc. ("Express Scripts") is a Delaware corporation that maintains its principal place of business in Missouri and is registered to do business in Puerto Rico. At all times relevant to this complaint, Express Scripts provided pharmacy benefit management services in Puerto Rico.

19. Express Scripts is a wholly owned direct subsidiary of Evernorth Health, Inc. and a wholly owned indirect subsidiary of Cigna Corporation.

20. At all relevant times, Express Scripts had agreements with various pharmaceutical manufacturers related to payments for preferred placement on Express Scripts standard formularies.

21. Prior to merging with Cigna in 2019, Express Scripts was the largest independent PBM in the United States. During the relevant period of this Complaint, Express Scripts controlled 30% of the PBM market in the United States.[7]

Defendant OptumRx, Inc.

22. Defendant OptumRx, Inc. ("OptumRx) is a California corporation that maintains its principal place of business in California and is registered to do business in Puerto Rico. At all times relevant to this complaint, OptumRx provided pharmacy benefit management services in Puerto Rico.

[6] Adam J. Fein, *The Top Pharmacy Benefit Managers of 2021: The Big Get Even Bigger*, Drug Channels (Apr. 5, 2022), https://www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html.
[7] *Id.*

23. At all relevant times, OptumRx had agreements with various pharmaceutical manufacturers related to payments for preferred placement on OptumRx's standard formularies.

24. During the relevant period of this Complaint, OptumRx controlled 21% of the PBM market in the United States.[8]

JURISDICTION AND VENUE

25. Plaintiff disputes that this Court has jurisdiction over this action pursuant to the Federal Officer Removal Statute, 28 U.S.C. § 1442. If and to the extent that such removal jurisdiction exists, however, Plaintiff concedes that this Honorable Court is the appropriate venue for this removed action and this Honorable Court has *in personam* jurisdiction over each of the Defendants.

Federal Officer Jurisdiction Does Not Exist

26. Defendants CVS Caremark and Express Scripts have contended that they are agents of federal officers acting under color of federal office for purposes of this action because they administer prescription drug claims on behalf of FEHBA and TRICARE, respectively.

27. To the extent Defendants contend they negotiate the terms of contracts for both federal and non-federal health benefit programs together, Defendants do so for their own convenience, and not as the result of any direction by the federal government or any federal officer.

28. No federal officer or federal agency directed CVS Caremark or Express Scripts to:

a. conduct rebate negotiations for FEHBA plans with non-FEHBA plans or TRICARE with non-TRICARE plans, respectively;

b. apply rebate negotiations applicable to FEHBA plans to non-FEHBA plans or TRICARE to non-TRICARE plans, respectively; or

[8] *Id.*

c. apply terms applicable to FEHBA plans to non-FEHBA plans or TRICARE to non-TRICARE plans, respectively.

29. Further, CVS Caremark and Express Scripts administer rebates and pharmacy claims on a plan-by-plan basis. This means that CVS Caremark and Express Scripts can identify and separate rebates and pharmacy claims attributable to FEHBA plans and TRICARE, respectively, from rebates and pharmacy-level claims attributable to other plans, including plans in Puerto Rico. The U.S. Office of Personnel Management ("OPM"), which sponsors FEHBA plans, contracts with health benefit plans (*e.g.*, Blue Cross Blue Shield, Kaiser Permanente). It does not contract with PBMs or require its health benefit plans to contract with PBMs. In the event health benefit plans do contract with PBMs, OPM requires them to ensure that PBMs adhere to certain transparency standards (attached as Exhibit A), including transparently disclosing and passing through rebates and other fees from manufacturers to the health benefit plans. But OPM imposes these standards only on FEHBA plans, not the plans that are the subject of this Complaint, which are exclusively non-federal health insurance and/or non-health benefits programs. Moreover, the OPM's transparency standards relate to PBMs' relationships with their clients (*e.g.*, health benefit plans), not PBMs' relationships with manufacturers or pharmacies.

30. Further, OPM does not dictate or place limits on the conduct that is the subject of this Complaint, including, but not limited to:

- negotiating rebates for non-federal health benefit plans;
- accepting rebates for non-federal health benefit plans;
- designing formularies for non-federal health benefit plans;
- determining which pharmacies must fill prescriptions for consumers with non-federal health benefit plans;

- negotiating reimbursement rates with pharmacies for non-federal health benefit plans; and
- reimbursing pharmacies for prescriptions relating to non-federal health benefit plans.

31. Pursuant to Express Scripts' contract with the Department of Defense, Express Scripts administers prescription drug benefits for TRICARE but does not negotiate rebates or design formularies for the Department of Defense or TRICARE.

BACKGROUND

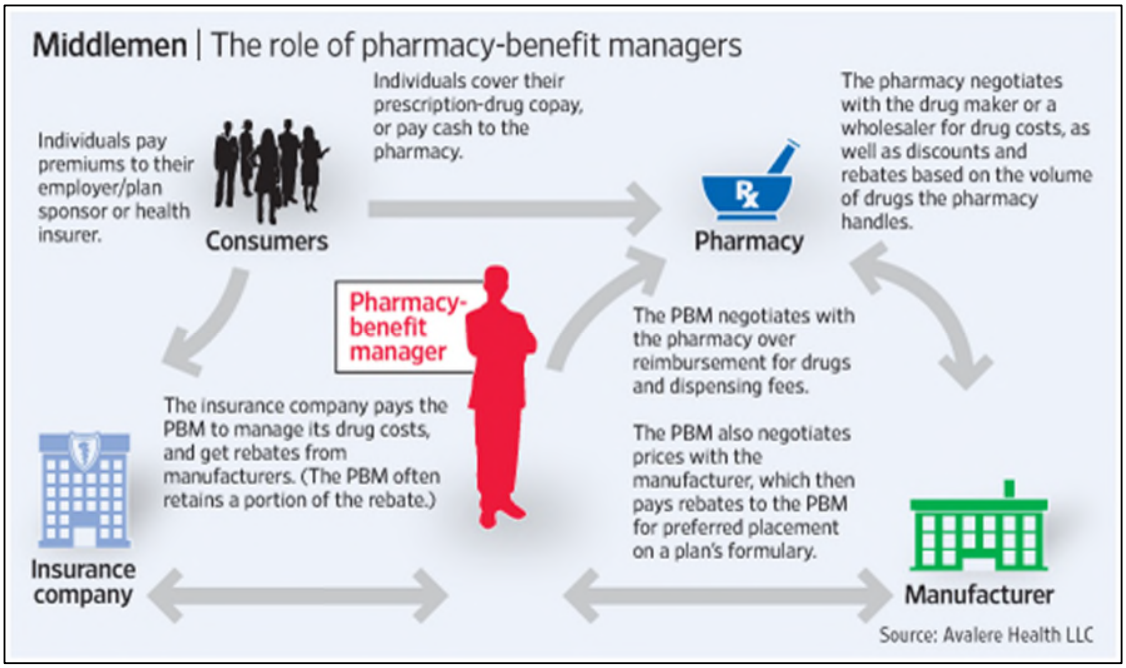
PBMs Are the Middleman in a Complex Drug Pricing System

32. Consumers pay monthly insurance premiums to their employers or insurance companies (third-party payers) that sponsor their health benefit plans. Health benefit plans then contract with PBMs to administer consumers' prescription drug benefits. Although PBMs may receive some compensation directly from health benefit plans, they are largely compensated through fees that drug manufacturers and pharmacies pay, as discussed below.

33. PBMs, including Defendants, act as intermediaries between health benefit plans and other entities in the drug distribution chain, such as prescription drug manufacturers and pharmacies (as shown in Figure 1 below).[9] PBMs are involved in, and benefit at, almost every step in this complex system—often secretly and unbeknownst to consumers, or even their own clients.

[9] Dan Fleshler, *Opening Up the Black Box on PBMs (Pharmacy Benefit Managers)*, Healthline (Sept. 21, 2018), https://www.healthline.com/diabetesmine/PBM-primer.

Figure 1: The Role of Pharmacy Benefit Managers



34. In their role as intermediaries, PBMs participate in the complex scheme of pricing and paying for prescription drugs. Various prices and benchmarks are used at different stages in the drug pricing system, including:

- **Wholesale Acquisition Cost ("WAC" or "list price")**: the manufacturer's published list price to wholesalers or direct purchasers (excludes rebates or other discounts)

- **Manufacturer's Net Price**: the revenue a manufacturer receives (*i.e.*, the list price (WAC) minus rebate or other discounts)

- **Average Wholesale Price ("AWP")**: the estimated average price that pharmacies pay to wholesalers (excludes rebates or other discounts), typically the manufacturer's list price (WAC) plus 20%

- **National Average Drug Acquisition Cost ("NADAC")**: the estimated wholesale price retail pharmacies pay to wholesalers, based on invoice prices paid by retailers

- **Maximum Allowable Cost ("MAC")**: PBMs' self-established upper limit of what they will reimburse pharmacies for generics

- **Usual and Customary Price ("U&C" or "cash price")**: the price that a pharmacy charges cash-paying consumers

PBMs Contract with Prescription Drug Manufacturers

35. PBMs negotiate and contract with manufacturers of brand-name prescription drugs for rebates and other fees in exchange for securing placement on PBMs' drug formularies, and for the position a drug enjoys on the PBM's formularies—either more advantageous to the manufacturer or less.

36. Prescription drug rebates are reductions from the list prices (WAC) that manufacturers pay after prescriptions are dispensed. Yet, unlike traditional point-of-sale rebates, manufacturers pay prescription drug rebates to PBMs, not to insured (or uninsured) consumers.

37. Manufacturers also pay PBMs "administrative fees" for administering rebates. Like rebates, administrative fees are tied to WAC (such that PBMs again benefit from higher drug prices) and paid according to PBMs' confidential contracts with manufacturers. Administrative fees typically range from 3% to 5% of WAC.[10]

38. "Price protection" is another way that PBMs extract payments from manufacturers. It is a cap on the amount by which prescription drug manufacturers can increase WAC for a particular drug (ranging from 0% to 12%).[11] Any price increase by manufacturers above the established cap triggers additional rebate payments to PBMs. These additional payments are known as price protection. While PBMs present price protection as a means to reduce costs, the evidence shows that PBMs have done little to accomplish that. Instead, drug prices have continued to skyrocket, despite the existence of so-called price protection. The price protection structure also

[10] Senate Finance Committee Insulin Report, *supra* note 4, at 82.
[11] *Id.* at 84.

creates another perverse incentive for PBMs. As with rebates, PBMs retain a portion of the price protection payments and pass the remainder through to health benefit plans.

39. A drug formulary is a list of generic and brand-name prescription drugs assembled by PBMs and thus covered by health benefit plans. A health benefit plan will not typically reimburse any part of the cost for a drug that is not included in the PBM-designed formulary.

40. Drug formularies are usually divided into tiers that determine the cost-share amounts (*e.g.*, the copayment or co-insurance) that consumers must pay toward the cost of a prescription. Lower tiers have lower cost-share amounts than higher tiers.

41. Generally, manufacturers of brand-name prescription drugs pay higher rebates for preferred formulary placement. This is because, upon information and belief, consumers are more likely to fill, and doctors are therefore more likely to write, prescriptions for drugs with lower cost-share amounts (and ask their doctors to prescribe products on lower formulary tiers).

42. The rebates PBMs negotiate are highly confidential. For the most part, the exact terms of the agreements between PBMs and prescription drug manufacturers are unknown to others in the supply chain, even to PBMs' own clients. Thus, for most of the players in the prescription drug supply chain, drug pricing is a black box.

43. Drug rebates and other fees paid to a PBM are usually based on list price (WAC). For example, a manufacturer may offer PBMs a rebate of 40% of WAC or an administrative fee of 3% of WAC for a particular drug. Thus, when WAC increases, rebates and fees also increase.

44. PBMs typically retain a portion of the payments they receive from prescription drug manufacturers and pass on the remainder to health benefit plans.

PBMs Contract with Pharmacies

45. In addition to negotiating and contracting with manufacturers for fees and rebates in determining what drugs to include in formulary coverage, PBMs negotiate and contract with

pharmacies to create networks of preferred pharmacies where consumers (which PBMs refer to as their "members") may fill prescriptions for these drugs. These agreements determine the amount PBMs will pay pharmacies to fill prescription drugs (minus any cost-share amounts that consumers pay directly to pharmacies).

46. Typically, PBMs mark up the price they pay to pharmacies when seeking reimbursement for those payments from health benefit plans—creating another revenue stream for PBMs, typically referred to as the "spread." To avoid confusion, this revenue source will be referred to hereinafter as the "PBM-to-pharmacy spread."

Consumers' Out-of-Pocket Costs Are Typically Tied to WAC

47. Consumers' out-of-pocket costs for drugs are determined by whether they have insurance and the terms of their coverage. Consumers pay, from high to low, either: (1) the cash price of the prescription drug (because consumers are either uninsured or in the deductible phase of coverage), to (2) a cost-share payment based on a percentage of drug costs (*e.g.*, 20% of the drug price), to 3) what is typically the least expensive option, a flat copayment, typically based on the drug's formulary tier.

48. Consumers without insurance pay the pharmacy's cash price, which is generally marked up above WAC. For example, in 2022, the WAC price for Lantus (manufacturer Sanofi's top-selling insulin) was $283.56 per vial and the average consumer's cash price for Lantus was $343 per vial.[12]

49. An increasing number of consumers have high-deductible plans, which require them to pay the cash price for drugs until they meet their deductible—averaging nearly $2,700 a

[12] Sanofi-Aventis U.S. LLC, *How much should I expect to pay for Lantus?*, https://www.lantus.com/-/media/EMS/Conditions/Diabetes/Brands/lantus-final/Header/Lantus-Pricing.pdf (last visited Feb. 11, 2022); Benita Lee, *How Much Does Insulin Cost? Here's How 28 Brands and Generics Compare*, GoodRx Health (Jan. 26, 2022),

year for single coverage in 2024, while 36% have a deductible of $3,000 or more.[13] Even those consumers with more modest deductibles are still adversely affected by higher drug costs until their deductibles are exhausted and coverage kicks in.

50. About 30–50% of insured consumers pay a coinsurance amount, which is a percentage of the full list price (WAC), not reduced by rebates.[14]

51. Other insured consumers pay a flat copayment amount, such as $5 for generic drugs and $10 for brand-name drugs that the PBMs give preferential treatment. The copayment is not directly tied to WAC; however, the overall cost of drugs factors into a plan's decision when determining health insurance premiums and consumer copayment amounts.

FACTUAL ALLEGATIONS

I. Defendants Conduct Trade and Commerce in Puerto Rico

52. Defendants are engaged in trade and commerce by, among other things, administering prescription drug benefits in Puerto Rico.

53. Defendants contract with health benefit plans based in and outside of Puerto Rico to provide services to Puerto Rico consumers. They are compensated through a combination of fees paid by health benefit plans, which are derived from consumers' premiums, and fees paid by drug manufacturers and pharmacies, which stem from consumers' drug utilization, as discussed above.

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https://www.goodrx.com/healthcare-access/research/how-much-does-insulin-cost-compare-brands.

[13] Gary Claxton et al., *Employer Health Benefits 2024 Annual Survey*, KFF (Oct. 9, 2024) at 140, https://files.kff.org/attachment/Employer-Health-Benefits-Survey-2024-Annual-Survey.pdf.

[14] Lisa L. Gill, *The Shocking Rise of Prescription Drug Prices: Here's why prices keep going up, plus how to combat the sticker shock—and still protect your health*, Consumer Reports (Nov. 26, 2019), https://www.consumerreports.org/drug-prices/the-shocking-rise-of-prescription-drug-prices/.

54. As CVS Caremark explains to consumers through its welcome kit: "We manage your prescription drug benefits just like your health insurance company manages your medical benefits."[15]

55. Defendants market their services to and interact directly with these consumer-patients. Moreover, even though Defendants do not have a direct contractual relationship with these consumers, they nonetheless are part of consumer transactions that are covered by 10 L.P.R.A. § 259. Indeed, the affected consumers are intended third-party beneficiaries of the contractual relationship between their health benefit plans and Defendants.

56. As an example of the relationship between Defendants and these Puerto Rico consumers, Defendants provide identification cards to these consumers with their company logos to present to pharmacies for the purpose of determining the consumers' prescription drug coverage.

57. Defendants also have consumer-facing websites in English and Spanish where they ask consumers to create accounts.[16] The websites also direct consumers to contact Defendants if they have questions regarding their prescription drug benefits.

58. Indeed, Defendants acknowledge their important role in serving consumers by advertising that consumers are their members and that their primary role is to serve members.

59. CVS Caremark represents in the "About Us" section of its website: "Your health is our priority[.] As a pharmacy benefit manager (PBM), we manage prescription plans to help make

[15] CVS Caremark, *Sample Welcome Kit*, (Jan. 18, 2023), https://benefits.vmware.com/wp-content/uploads/2018/10/CVS-Caremark-Sample-Welcome-Kit_ID-Card.pdf, [https://web.archive.org/web/20230118161133/https://benefits.vmware.com/wp-content/uploads/2018/10/CVS-Caremark-Sample-Welcome-Kit_ID-Card.pdf].

[16] CVS Caremark, https://www.caremark.com (last visited Dec. 13, 2024); Express Scripts, https://www.express-scripts.com (last visited Dec. 13, 2024); OptumRx, https://www2.optumrx.com (last visited Dec. 13, 2024).

them more cost-effective – so you can get what you need when you need it."[17] In 2023, Caremark advertised that it served 103 million members.[18]

60. Express Scripts promises that it "advocate[s] on behalf of members, removing barriers to access and simplifying every care experience."[19] It also represents that it provides "[p]harmacy benefits that benefit you[.]"[20] Express Scripts states on its website that it serves "1 in 3 Americans."[21]

61. OptumRx states on its website: "Optum Rx is a pharmacy benefit manager serving more than 65 million members. We provide safe and cost-effective ways for you to access your medications and help you achieve better health outcomes."[22]

II. Defendants Deceptively Represent That They Act to Serve Consumers by Lowering Drug Prices and Ensuring Their Access to Safe and Effective Drug Treatments

62. Defendants make numerous deceptive representations directly and indirectly to consumers regarding Defendants' role in the market. In particular, Defendants deceptively represent that: (1) they function to lower drug costs; (2) their formularies are designed to maximize effectiveness and safety and minimize cost; and (3) they are acting in consumers' best interest.

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[17] CVS Caremark, *About Us*, https://www.caremark.com/about-us.html (last visited Dec. 13, 2024).
[18] CVS Caremark, *About Us*, https://www.caremark.com/about-us.html (Oct. 11, 2023), https://www.caremark.com/about-us.html, [https://web.archive.org/web/20231011205254/https://www.caremark.com/about-us.html].
[19] Evernorth Health Services, *Express Scripts By Evernorth*, https://www.evernorth.com/our-solutions/express-scripts-pbm (last visited Dec. 13, 2024).
[20] Express Scripts, *Benefits*, https://www.express-scripts.com/pharmacy-benefits-manager (last visited Dec. 13, 2024).
[21] Evernorth Health Services, *The Value Express Script Delivers*, https://www.evernorth.com/esfacts/key-topics/the-value-express-scripts-delivers (last visited Dec. 13, 2024).
[22] OptumRx, Inc., *Welcome to Optum Rx* (April 1, 2024), https://welcome.optumrx.com/standard/getstarted [https://web.archive.org/web/20240401195432/https://welcome.optumrx.com/standard/getstarted].

63. Defendants make these deceptive representations directly to consumers through their consumer-facing websites, other online materials, and, most recently, in the case of Express Scripts, newspaper advertisements. Upon information and belief, Defendants also make these deceptive representations directly to consumers through other consumer-facing materials, such as welcome kits, benefit handbooks, published formularies, and letters. In addition, upon information and belief, Defendants make these deceptive representations to health benefit plans with the knowledge and intention that the health benefit plans will pass this misinformation on to consumers.

64. For example, CVS Caremark falsely represents that its role is to "keep prescription drugs affordable."[23] It also misleadingly claims:

- "MYTH: Rebates negotiated by PBMs are driving up the prices of prescription drugs for consumers and plan sponsorship. FACT: Pharmaceutical manufacturers set the list price for a given drug. PBMs then negotiate with manufacturers to secure the drug at a lower cost for their plan sponsors and their members."[24]
    - This representation is likely to mislead consumers because CVS Caremark conceals the manner in which its tactics incentivize and/or pressure manufacturers to increase the price of their drugs in order to maintain a reasonable profit margin while satisfying the demands of PBMs (including CVS Caremark) for ever-increasing rebates and fees.

- "MYTH: PBMs increase cost-sharing burdens for beneficiaries. FACT: Plan designs are determined by clients – employers and health insurance plans – who decide how they subsidize their members' coverage."[25]
    - This representation is likely to mislead consumers because it conceals from consumers the fact that the consumer's share of the costs is sometimes tied to the list price (WAC) of the applicable drugs, and if CVS Caremark pressures a manufacturer to pay higher rebates and fees, resulting in higher

[23] CVS Health, *5 Facts to Know About PBMs*, https://business.caremark.com/content/dam/enterprise/business-caremark/insights/pdfs/2023/PBM-5-facts_r4%20(1).pdf, at 1 (last visited Dec. 15, 2024).
[24] CVS Health, *Myths vs. Fact Pharmacy Benefit Management* (June 7, 2022), at 2, https://www.cvshealth.com/sites/default/files/cvs-health-myth-vs-fact-pbm-2021-01.pdf, [https://web.archive.org/web/20220607092208/https://www.cvshealth.com/sites/default/files/cvs-health-myth-vs-fact-pbm-2021-01.pdf].
[25] *Id*. at 3.

drug prices for the manufacturer to maintain a reasonable profit margin, the consumer's cost share rises as well, like a boat on a rising sea.

- "MYTH: PBMs lower drug costs by restricting patient access to needed medication. FACT: PBMs help ensure that beneficiaries have access to the prescriptions they need to stay healthy, at a price they can afford."[26]
    - This representation is likely to mislead consumers because CVS Caremark makes certain formulary decisions based primarily on what will increase its revenues, not on providing consumers with the widest range of drugs for their conditions, at the lowest possible cost.

- "A formulary is your plan's list of covered medications. The formulary is designed to help you get the medication you need at the lowest possible cost."[27]
    - This representation is likely to mislead because the formularies designed by CVS Caremark have the intent and/or effect of increasing the cost to at least a subset of consumers and giving preferential treatment to many drugs based on factors unrelated to the health or safety of the patient.

- "Formularies have two primary functions: 1) to help provide pharmacy care that is clinically sound and affordable for plans and their plan members, and 2) to help manage drug spend through the appropriate selection and use of drug therapy."[28]
    - This representation is likely to mislead consumers for the reasons stated above.

- "Your health is our priority[.] As a pharmacy benefit manager (PBM), we manage prescription plans to help make them more cost-effective – so you can get what you need when you need it."[29]
    - This representation is likely to mislead consumers for the reasons stated above.

65. For example, Express Scripts incorrectly asserts that it "exists to lower the cost of medications."[30] Like CVS Caremark, Express Scripts deceptively makes the following assertions,

[26] *Id.* at 4.
[27] CVS Caremark, *Your plan's formulary*, https://www.caremark.com/plan-benefits.html (last visited Dec. 15, 2024).
[28] CVS Caremark, *Formulary Development and Management at CVS Caremark*, https://www.caremark.com/portal/asset/FormDevMgmt.pdf, at 1 (last visited Dec. 15, 2024).
[29] CVS Caremark, *About Us*, https://www.caremark.com/about-us.html (last visited Dec. 15, 2024).
[30] Evernorth Health Services, *The Reality of Rebates*, (Aug. 28, 2024) https://www.evernorth.com/esfacts/key-topics/the-reality-of-rebates, [https://web.archive.org/web/20240828214339/https://www.evernorth.com/esfacts/key-topics/the-reality-of-rebates].

which are likely to mislead consumers for the same reasons as stated with respect to CVS Caremark:

- "PBMs help get the lowest net cost for their clients and consumers. Claims that 'higher rebates mean higher prices' have been repeatedly debunked and repeatedly disproven."[31]

- "Rebates help defray ever-rising drug costs for Express Scripts clients and consumers"[32]

- "Rebates do not raise drug prices, drug makers raise drug prices, and they alone can lower them. Consider the cost of Humalog® (insulin lispro): over the past seven years, the list price for this medication has increased dramatically, yet the net cost has remained relatively constant. Without PBMs, and specifically without Express Scripts, plan sponsors would have paid exponentially more for their prescription drugs."[33]
- "FACT: Public disclosure of negotiated rebates will not lower prescription drug costs. #PBMs Express Scripts negotiates with drug manufacturers to increase competition and lower costs for patients."[34]

- "Express Scripts revises its [National Preferred Formulary ("NPF")] every year, based on reviews of research about the medical value of medicines and their costs. The process of reviewing the NPF and making yearly updates is designed to give members access to the most effective medicines at the lowest possible prices."[35]

- "Pharmacy benefits that benefit you[.] Your pharmacy benefits should be as personal as your medication. You can depend on Express Scripts for care that fits your specific needs."[36]

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[31] *Id.*
[32] *Id.*
[33] Express Scripts, Inc., *The Rebate Debate* (June 29, 2017), https://www.express-scripts.com/corporate/articles/rebate-debate, [https://web.archive.org/web/20231211181605/https://www.express-scripts.com/corporate/articles/rebate-debate].
[34] @ExpressScripts, Twitter (Apr. 9, 2019, 3:10 PM), https://twitter.com/ExpressScripts/status/1115693403285741568.
[35] Express Scripts, *National Preferred Formulary (NPF)*, https://www.express-scripts.com/frequently-asked-questions/national-preferred-formulary-npf (last visited Sept. 5, 2024).
[36] Express Scripts, *Benefits*, https://www.express-scripts.com/pharmacy-benefits-manager (last visited Sept. 5, 2024).

66. In addition, on September 11, 2024, Express Scripts ran a print advertisement in the Wall Street Journal, declaring:

> WE'RE PHARMACISTS.
> WE'RE CLINICIANS.
> WE'RE RESEARCHERS.
> WE'RE NEGOTIATORS
> WE'RE CAREGIVERS.
> THAT'S NOT
> A MIDDLEMAN.
> THAT'S AN
> ADVOCATE.
> We're Express Scripts by Evernorth. We're not middlemen. We're 18,000 advocates who take pride in being the last line of defense for millions of Americans against rising health costs. Fighting every day to make their medications more affordable and accessible.

67. Express Scripts also ran a print advertisement in the New York Times on August 29, 2024 with the tagline: "Pharmaceutical companies raise drug prices. We lower them." The advertisement also stated: "In 2023, big pharma increased prices for 60% of all branded drugs. Why? Because they can. At Express Scripts, we fight back. We are the last line of defense for nearly 100 million Americans against skyrocketing health costs." These statements are deceptive for the same reasons stated above.

68. OptumRx is no better. It falsely represents: "PBMs don't cause high drug costs – they're part of the solution."[37] It also misleadingly states:

- "Rebates are a longstanding tool used by PBMs to negotiate with drug manufacturers to achieve lower prescription drugs costs for clients."[38]
- "Unfortunately, many people do not take their medications as they should, citing cost as a primary reason. Optum Rx is directly addressing this problem by always driving lowest net cost across our book of business."[39]

[37] OptumRx, *Experts agree: PBMs add value, lower costs* (Oct. 25, 2023), https://www.optum.com/en/business/insights/pharmacy-care-services/page.hub5.pharmacy-benefit-managers-medication-affordability.html.
[38] OptumRx Inc., *Regulatory developments affecting pharmacy* (Feb. 2022), https://www.optum.com/business/resources/library/regulatory-updates-q1-2022.html.
[39] *Id.*

- "A formulary is a list of prescribed medications or other pharmacy care products, services or supplies chosen for their safety, cost, and effectiveness."[40]

- "Both PBMs and their clients are aligned on the need to implement benefit designs that promote generics. The reason is simple: the programs save money and help promote better health outcomes."[41]

- "Pharmacy benefit managers (PBMs) like Optum Rx help consumers and customers access the most effective medicines at the most affordable costs. We serve as a counterweight to the substantial market power of pharmaceutical manufacturers, who have sole discretion over how they price their products. Through our negotiations with manufacturers and by offering clinical and cost management services, we are lowering the cost of prescription drugs and improving health outcomes for our customers, including employers, unions, health plans, governments and the consumers they serve."[42]

- "For every $1 spent on their services, PBMs reduce cost by $10."[43]

69. OptumRx's representations are likely to mislead consumers for the same reasons as stated with respect to Express Scripts and CVS Caremark.

70. The fallacy of Defendants' contention that drugs with higher WAC prices with large rebates are equivalent in cost to or cheaper than drugs with lower WAC prices with lower or no rebates is disingenuous and not supported by the facts—or the math. For example, if you compare a drug with a $50 WAC price and no rebate and the same drug with a $100 WAC price and a $50 rebate (or combination of rebate and other fees), this sounds deceptively like both drugs have the same net price: $50. But this ignores the fact that the PBMs retain some portion of the fees they negotiate from manufacturers—sometimes a very significant portion. In the above

[40] *Id.*
[41] OptumRx, Inc., *Experts agree: PBMs add value, lower costs* (Oct. 25, 2023), https://www.optum.com/en/business/insights/pharmacy-care-services/page.hub5.pharmacy-benefit-managers-medication-affordability.html.
[42] OptumRx, Inc., *Pharmacy Care That Provides Affordable Prescription Medications and Therapies*, https://www.unitedhealthgroup.com/ns/optum-rx.html (last visited Dec. 15, 2024).
[43] *Id.*

example, if the PBM retains $10 of the $50 rebate or other fees, the $100 drug now has a net price of $60—making it more expensive than the $50 drug with no rebate. In addition, as explained above, many consumers' cost-share amounts are tied to WAC, meaning their out-of-pocket costs will rise along with the WAC price, even if the net cost to the health benefit plan is lowered.

71. As discussed above and explained in more detail below, this information is material to consumers and Defendants' representations are misleading and do not accurately reflect Defendants' role in the market, their decision-making with regard to their formularies, or their impact on drug prices.

III. Defendants Engage in a Scheme to Artificially Inflate Drug Prices for Their Own Financial Gain

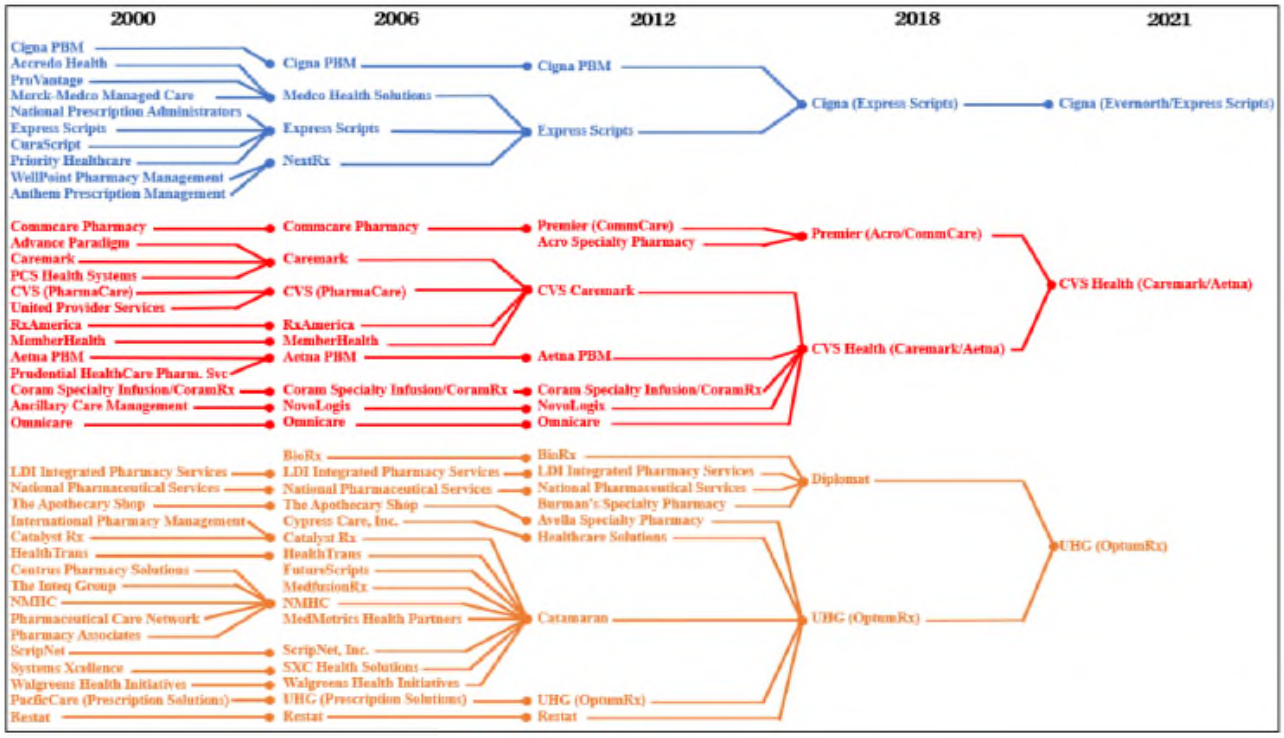
72. The PBM industry is heavily concentrated. The three largest PBMs are: (1) CVS Caremark (owned by CVS Health, which also owns CVS Pharmacy—the largest retail pharmacy chain in the United States); (2) Express Scripts (owned by Cigna—a global health insurance company); and (3) OptumRx (owned by UnitedHealth Group—a healthcare and insurance company).

73. Through their multiple lines of businesses, each of these companies exercise extraordinary influence in health care. They are among the Fortune 500 top 16 companies. UnitedHealth Group is listed 4th—below only Walmart, Amazon, and Apple, CVS Health is listed 6th—above Alphabet (Google's parent company) and Costco. And, Cigna is listed 16th—above Ford, Bank of America, and Meta.

74. Due to a series of mergers and acquisitions, the big three PBMs—Defendants—now have ***very little competition*** and collectively manage ***80%*** of drug benefits, covering more than ***220 million Americans***, making preferred placement on their drug formularies a significant

bargaining chip when negotiating payments from prescription drug manufacturers (*see* Figure 2 below showing corporation consolidations).[44, 45]

Figure 2: PBM Parent Entity Consolidation



75. Defendants began increasingly exerting their leverage in 2012 by excluding drugs from certain therapeutic classes from their formularies to intensify the rebates manufacturers offered them. The threat of exclusion fundamentally changed drug pricing. Rebates went from modest discounts to steep payments that manufacturers were all but forced to make because not paying Defendants could doom a drug's chance of success. Over time, rebates have become a significant factor that manufacturers consider when setting drug prices.

[44] Senate Finance Committee Insulin Report, *supra* note 4, at 68.
[45] Arkansas ex rel. Rutledge v. Eli Lilly & Co., No. 60cv-22-2976, Compl. ¶ 312 (Ark. Pulaski County Cir. Ct. May 11, 2022), https://content.govdelivery.com/attachments/ARAG/2022/05/11/file_attachments/2156162/2022-05-11-%20Insulin%20Complaint%20FINAL%20DRAFT.pdf.

A. Defendants Exclude Drugs from Their Formularies to Increase Their Own Rebates and Fees

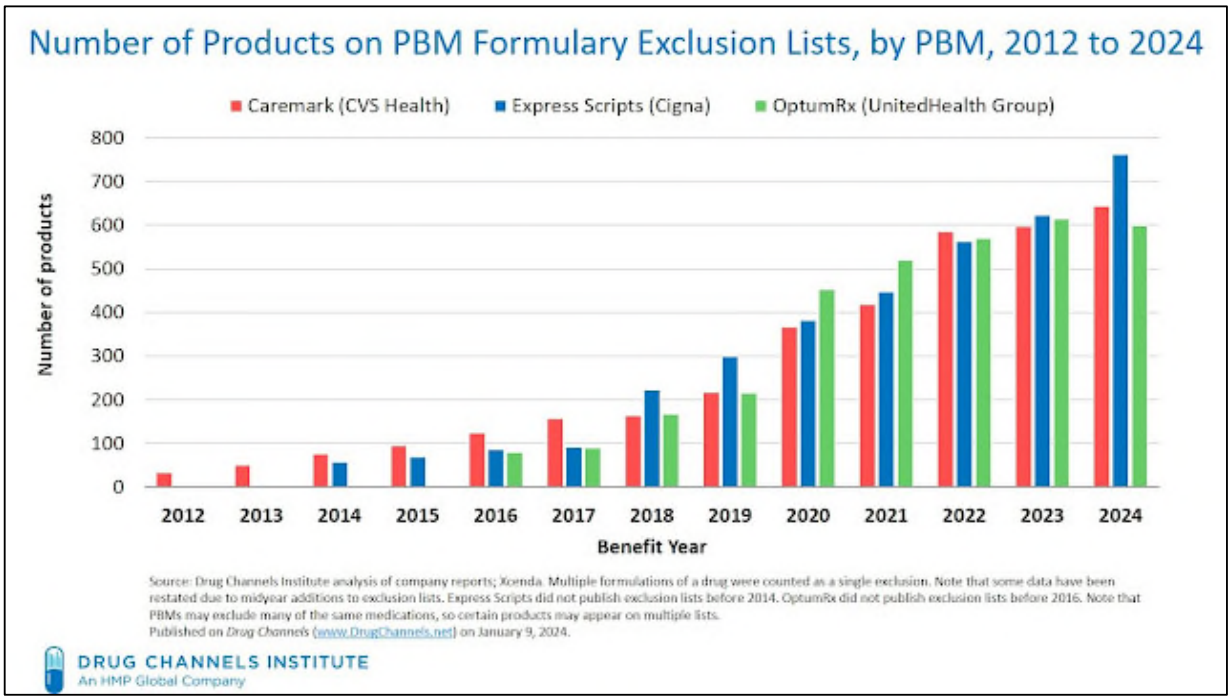
76. Contrary to their representations that they design formularies to minimize costs and maximize effectiveness and safety, Defendants' decisions about formulary coverage for drugs is largely driven by their own profits and have the effect of sometimes excluding the most inexpensive and even the most effective and safest treatments (and driving up drug prices).

77. Defendants profit directly and indirectly from rebates: directly by retaining rebates (and, increasingly, other fees) from manufacturers, and indirectly by competing for business based on the misleading impression that their ability to deliver the highest rebates to health benefit plans will result in the lowest net cost (as explained above). As a result, Defendants focus on drugs that deliver the highest rebates.

78. Defendants extract higher rebates from manufacturers by promising to shift nearly all of their "members" (*i.e.*, consumers) to the manufacturers' drugs and away from competing drugs. Defendants do this by requiring health benefit plans to follow their standard formularies. If health benefit plans want to deviate from the standard formulary and adopt customized formularies, which threaten Defendants' ability to profit from the highest rebates, they face substantial costs. Moreover, many health benefit plans cannot cost-effectively devote the resources and/or pharmaceutical expertise necessary to develop their own formularies and negotiate prices for the drugs on those formularies with manufacturers, which is why they outsource formulary decisions to Defendants and accept their standard formularies.

79. CVS Caremark started excluding drugs from its formulary in 2012. Express Scripts and OptumRx began the practice in 2014 and 2016, respectively (*see* Figure 3 below showing the dramatic increase in the number of exclusions by Defendant per year).[46]

Figure 3: Defendant Formulary Exclusions from 2012-2024



80. A recent study looked at drug utilization restrictions on prescription drugs from 2011–2020 in Medicare Part D plans.[47] It found that in 2020, beneficiaries' access to drugs in unprotected classes (*i.e.*, not in classes of drugs that Medicare Part D plans are required to cover) was restricted either through formulary exclusions, prior authorization, or step therapy requirements (*i.e.*, conditioning the prescription of certain drugs on first trying a different, usually

[46] Adam J. Fein, *The Big Three PBMs' 2024 Formulary Exclusions: Biosimilar Humira Battles, CVS Health's Weird Strategy, and the Insulin Shakeup*, Drug Channels (Jan. 9, 2024), https://www.drugchannels.net/2024/01/the-big-three-pbms-2024-formulary.html.
[47] Joyce et al., *supra* note 2, at 391.

less expensive drug) on an average of 40% of available drugs.[48] Upon information and belief, Defendants' non-Medicare plans are equally (if not more) restrictive.

81. Because exclusions were so profitable for Defendants, the number of medicines excluded from Defendants' formularies increased 961% from 2014 (109 unique drug exclusions) to 2022 (1,156 unique drug exclusions).[49] Drugs used to treat chronic conditions—including insulin, antidepressants, antipsychotics, and antiarrhythmics—are most frequently excluded by Defendants, which means Defendants' unfair and deceptive restriction of these drugs may have long-term adverse consequences for the consumer-patients who require them.

82. Since Defendants began excluding drugs from their formularies, the monetary value of rebates has skyrocketed. For example, in July 2013, the manufacturer Sanofi offered rebates for insulin products between 2% and 4% for placement on CVS Caremark's formulary. By contrast, in 2018, Sanofi's rebates for insulin products were as high as 56%.[50]

83. The overall amount prescription drug manufacturers paid in rebates and other fees nationally doubled from 2013 ($83 billion) to 2018 ($166 billion).[51]

84. Defendants argue that their conduct in excluding drugs reduces costs, but the evidence indicates otherwise. A study from the Tufts Center for the Study of Drug Development found that cost-effectiveness did not appear to correlate with a drug's excluded or recommended status; rather, rebates appeared to play the more significant role in determining exclusion and

[48] *Id*. at 396.
[49] Xcenda, *Skyrocketing growth in PBM formulary exclusions continues to raise concerns about patient access* (May 2022) at 2, https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_pbm_exclusion_may_2022.pdf.
[50] Senate Finance Committee Insulin Report, *supra* note 4, at 67.
[51] Gill, *supra* note 14.

recommendation decisions.[52] The Tufts study conducted a head-to-head comparison of excluded versus recommended drugs in the same therapeutic class. In half the drugs examined, the more cost-effective drug was excluded from coverage. Consistent with Defendants' market rationale and marketing, that should not have happened even once, and the decisions are more plausibly explained by the influence of rebates.

85. Between 2019 and 2022, the three big insulin manufacturers launched low WAC price versions of their top selling products.[53] These products had WAC prices 50–60% below the brand-name products. Yet, Defendants gave preferential formulary treatment to the brand-name products with high rebates and excluded the medically equivalent, low WAC price versions with little or no rebates.

86. Internal documents from Novo Nordisk (another large insulin manufacturer) show that in 2018 the company considered, but ultimately decided against, lowering WAC for its insulin products by 50%.[54] The company's pricing committee warned that reducing WAC posed a significant financial risk to the company—even though the manufacturer's net price (and revenue) would remain the same. One of Novo Nordisk's primary concerns was facing retributive action from other entities in the pharmaceutical supply chain that derive payments based on WAC

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[52] Joshua P. Cohen et al., *Rising Drug Costs Drive the Growth of Pharmacy Benefit Managers Exclusion Lists: Are Exclusion Decisions Value-Based?*, 53 (Supp 1) Health Servs. Rsch. 2758, 2767, 2764 (Aug. 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6056588/pdf/HESR-53-2758.pdf.

[53] Eli Lilly & Company, *Lilly's Lower-Priced Insulin Now Available* (May 22, 2019), https://investor.lilly.com/news-releases/news-release-details/lillys-lower-priced-insulin-now-available; Novo Nordisk Inc., *Novo Nordisk's new insulin affordability offerings now available in the US* (Jan. 2, 2020), https://www.novonordisk-us.com/media/news-archive/news-details.html?id=36628; Sanofi, *Sanofi to lower out-of-pocket cost of insulin for uninsured patients and expand access in underserved communities* (June 29, 2022), https://www.news.sanofi.us/2022-06-29-Sanofi-to-lower-out-of-pocket-cost-of-insulin-for-uninsured-patients-and-expand-access-in-underserved-communities.

[54] Senate Finance Committee Insulin Report, *supra* note 4, at 61–63, Appendix 3 p. 206–212.

(namely, PBMs). Novo Nordisk specifically identified as downsides "formulary removal" and "CVS, Express Scripts, & Optum push to be kept whole." In other words, based on its experience and observation of market factors, Novo Nordisk had reason to be concerned that if it set the WAC for its insulin products at their true costs (Novo Nordisk's net price) instead of an inflated price with a 50% rebate, Novo Nordisk risked being removed from Defendants' formularies or having to pay Defendants their cut of the now eliminated 50% rebate.

87. In fact, when Novo Nordisk lowered the WAC price for its long-acting insulin Levemir by 65% in early 2023, Defendants removed Levemir from their formularies.[55] Levemir went from being accessible to 90% of insured consumers to 36% of insured consumers. In other words, 64% of insulin patients lost access to this cost-effective drug because of Defendants' market manipulation. As a direct result of the impact of these unfair and deceptive tactics on the market, Novo Nordisk began phasing out Levemir in late 2023 and ultimately discontinued it, and ***all*** insulin patients lost access to this cost-effective medication.

88. In some instances, Defendants give preferential formulary treatment to products that are more expensive ***and*** have seemingly inferior safety profiles. For example, in 2020, Express Scripts excluded AstraZeneca's Calquence (drug used to treat Chronic Lymphocytic Leukemia) in favor of the higher-priced Imbruvica (manufactured by AbbVie and Johnson & Johnson)—perhaps the first major PBM restriction of an oncology therapy. This is particularly troubling because significantly fewer people who took Calquence suffered atrial fibrillation compared to Imbruvica in a head-to-head trial.[56]

[55] Dani Kass, *Novo Nordisk Tells Sens. Ozempic Costs Are Linked To PBMs*, Law360 (Sept. 24, 2024), https://www.law360.com/health/articles/1871338/novo-nordisk-tells-sens-ozempic-costs-are-linked-to-pbms.

[56] Arlene Weintraub, *Express Scripts axes Novartis' psoriasis drug in favor of Lilly's as discounting takes over: analyst*, Fierce Pharma (Aug. 20, 2020),

89. Often, even products CVS Caremark recommends or gives preferential formulary treatment to are excluded by Express Scripts, and vice versa—further indicating that these exclusions are not evidence- or value-based.[57] Notably, Defendants' justifications for formulary exclusions are not ordinarily shared with consumers, their doctors, or even Defendants' clients (health benefit plans).

90. The only reasonable explanation for Defendants' actions is that the higher list prices (WAC) are tied to higher rebates and/or other payments to Defendants. If Defendants were truly passing through 100% of payments from manufacturers to health benefit plans, there would be no incentive for Defendants to give preferential treatment to drugs with higher WAC prices and higher rebates versus comparable drugs with lower WAC prices and lower rebates (*i.e.*, preferring a $100 brand-name drug with a 50% rebate over a $50 generic drug with no rebate).

91. In addition to excluding drugs, Defendants manipulate the formulary tiered system by giving preferential treatment to higher cost drugs for Defendants' own financial gain. According to their own marketing, PBMs are supposed to prefer less expensive drugs and save consumers and health benefit plans money. One key strategy would be placing these drugs in tiers with lower copayments, which would incentivize prescribers and consumers to utilize them, rather than higher-cost drugs, which raise prices for consumers and health benefit plans. However, a 2021 study reviewing Medicare claims data from approximately one million patients between 2010 and 2017 reveals the underlying economic dynamics and found the opposite is true.[58] The percentage

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https://www.fiercepharma.com/pharma/express-scripts-axes-novartis-psoriasis-drug-favor-lilly-s-as-discounting-takes-over-analyst; John C. Byrd, et al., *First results of a head-to-head trial of acalabrutinib versus ibrutinib in previously treated chronic lymphocytic leukemia*, 39(15) J. Clin. Oncol. 7500 (May 28, 2021), https://ascopubs.org/doi/abs/10.1200/JCO.2021.39.15_suppl.7500.

[57] Cohen et al., *supra* note 52, at 2764.

[58] Robin Feldman, *The devil in the tiers*, J. Law Biosci, Jan–Jun 2021, at 1 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8109230/.

of generic drugs on the least expensive tier dropped from 73% in 2010 to 28% in 2017. Further, the percentage of drugs on less economical, higher-cost tiers rose from 47% in 2010 to 74% in 2017. The list prices (WAC) for brand-name drugs are typically significantly higher than the list price for generic drugs; thus, it is unlikely that rebated brand-name drugs have an equivalent or lower net cost than their generic counterparts. From 2010–2017, tier misplacement cumulatively cost Medicare and the patients involved in the study $13.25 billion.

92. A study from the United States Government Accountability Office came to a similar conclusion.[59] It found that generic counterparts for 40 highly rebated brand-name drugs were less likely to be included or given preferred placement over the brand-name drug on Part D formularies compared to generic counterparts for other brand-name drugs.

93. Upon information and belief, the same incentives lead to the same results for non-Medicare plans, where Defendants have even more leeway.

94. To put the cost difference into perspective, about 80% of drug spending in the United States is attributable to a small number of high-cost, brand-name drugs, despite the fact that only 9% of prescriptions in the United States are filled for brand-name drugs. [60]

B. Defendants' Rebate Tactics Lead to WAC Price Inflation

95. Contrary to their representations that they lower costs for consumers, Defendants know their formulary-enabled rebates have the effect of driving up drug prices.

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[59] U.S. Gov't Accountability Off., *Medicare Part D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending* (Sept. 2023) at 27, https://www.gao.gov/assets/gao-23-105270.pdf.

[60] U.S. Dept. of Health and Human Services, *Trends in Prescription Drug Spending, 2016–2021* (Sept. 2022) at 1, https://aspe.hhs.gov/sites/default/files/documents/88c547c976e915fc31fe2c6903ac0bc9/sdp-trends-prescription-drug-spending.pdf; U.S. Food & Drug Admin., *Office of Generic Drugs 2022 Annual Report* (Jan. 2022) at 1, https://www.fda.gov/media/165435/download?attachment.

96. Manufacturers compensate for rising rebates by increasing WAC to maintain their profit margins. Over time, the gap between WAC and the net price (the price manufacturers receive for selling drugs) has become significant and reflects the role of rebates and other fees that PBMs demand in driving up drug prices. Today, WAC prices bear little resemblance to the true cost of prescription drugs. This has a tremendous negative impact on uninsured consumers paying full WAC prices and insured consumers satisfying deductibles or paying coinsurance tied to WAC.

97. When the CEO of Novo Nordisk—one of the big three insulin manufacturers—testified before Congress about the pricing of Ozempic and Wegovy, he admitted that list prices are set to accommodate PBMs' financial demands: "It is not our intention that anyone should pay the list price. The list price is the starting point for our negotiation against the PBMs and insurance companies."[61] Yet, some Puerto Rico residents are stuck doing just that, because they are either uninsured or satisfying a deductible and paying the full WAC (*i.e.*, list) price or making a cost-share payment that is tethered to the artificially inflated WAC price. For example, it is estimated that over 350,000 elderly people on the island do not have insurance that covers prescription drugs.[62]

98. In response to a 2023 survey, 67% of manufacturers perceived WAC-based fees, such as rebates and administrative fees, as a barrier to lowering WAC prices.[63] However, there is

[61] Kass, *supra* note 55.
[62] Ileanexis Vera Rosado, *Gran reto la accesibilidad de los medicamentos: Mientras el precio es cada vez mayor, el ingreso disponible para costearlo es cada vez menor*, EL VOCERO (Oct. 6, 2019), https://www.elvocero.com/economia/gran-reto-la-accesibilidad-de-los-medicamentos/article_2ab928d6-8b79-11e9-990d-4742561988f3.html.
[63] Eric Percher, *Trends in Profitability and Compensation of PBMs & PBM Contracting Entities*, Nephron Research (Sept. 18, 2023) at 13, https://nephronresearch.com/trends-in-profitability-and-compensation-of-pbms-and-pbm-contracting-entities/.

no valid reason to tie PBMs' fees to drug prices because the services PBMs perform are the same regardless of whether the drug has a high cost or low cost.

99. From 2011 to 2019, payments from prescription drug manufacturers (mostly rebates to PBMs) nearly tripled.[64] In 2011, a sample of 13 manufacturers paid 29.2% of their net revenue ($50.1 billion) to PBMs and other intermediaries to generate $171.8 billion in net sales. By 2019, the same manufacturers paid more than twice that amount: 67.4% of net revenue ($141.4 billion) to generate $209.9 billion in net sales.

100. In January of 2021, the United States Senate Finance Committee released a report detailing a bipartisan investigation into the skyrocketing price of insulin. One of the report's key findings is that WAC prices for insulin rose sharply between 2013 and 2019 in step with an exponential increase in rebates for these products.[65]

101. In 2023, gross drug sales at WAC prices totaled $917 billion, but manufacturers received less than half of that on average ($435 billion),[66] which far overshadows the $96 billion spent by manufacturers for research and development in 2023.[67] The balance ($482 billion) consists of (1) rebates and other discounts; (2) PBM fees and profits; and (3) consumers' out-of-pocket payments.[68]

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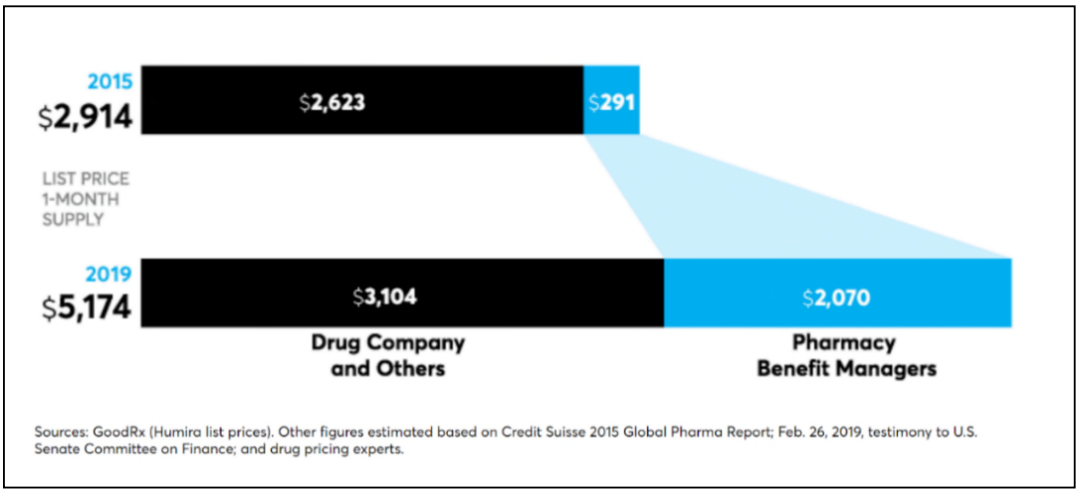
[64] Gill, *supra* note 14.
[65] Senate Finance Committee Insulin Report, *supra* note 4, at 7.
[66] The IQVIA Institute, *The Use of Medicines in the U.S. 2024: Usage and Spending Trends and Outlook to 2028* (Apr. 2024) at 44, 44, 42, https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2024.
[67] Matej Mikulic, *R&D Expenditure of the U.S. pharma industry (PhRMA members) from 1980 to 2023* (Sept. 2, 2024), https://www.statista.com/statistics/265055/us-pharmaceuticals-spending-on-research-and-development/.
[68] The IQVIA Institute, *supra* note 66, at 60.

102. Humira, AbbVie's blockbuster rheumatoid arthritis drug, is a good example of WAC inflation (as shown in Figure 4 below).[69] Humira's WAC increased 78% from 2015 to 2019.[70] Most of the WAC increase is attributable to rebates—which grew over 600% during this period. In sharp contrast, the net price AbbVie received for Humira only grew about 18% (from $2,623 to $3,104 in 2019).

Figure 4: Humira Price Increase from 2015–2019



103. A 2020 study found that for prescription drugs sold from 2016 to 2018, on average, a $1 increase in rebates was associated with a $1.17 increase in WAC.[71]

104. Defendants claim that prescription drug manufacturers—not Defendants—are responsible for inflating list prices (WAC). This is misleading. Manufacturers may set list prices for their drugs, but Defendants indirectly control list prices by negotiating drug rebates so high that manufacturers must raise their prices to maintain their revenue and profit margins. The close

[69] Gill, *supra* note 14.
[70] *Id.*
[71] Neeraj Sood et al., *The Association Between Drug Rebates and List Prices*, USC Schaeffer Center (Feb. 11, 2020), at 1, https://healthpolicy.usc.edu/wp-content/uploads/2020/02/SchaefferCenter_RebatesListPrices_WhitePaper-1.pdf.

correlation, over time, between the rise in WAC prices and the rise in rebates makes the causal connection between rebates and drug prices clear.

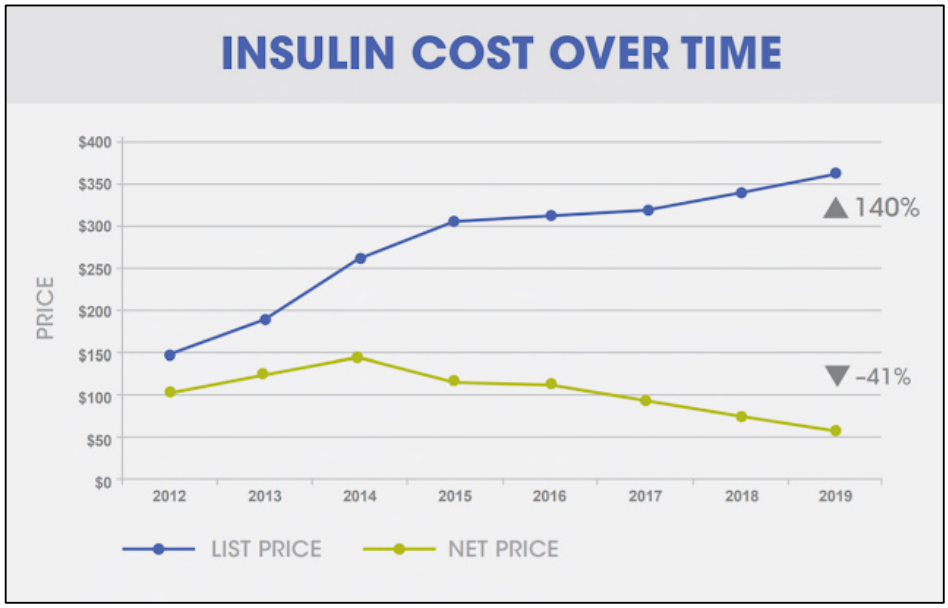
105. In January of 2022, before the Tenth Circuit Court of Appeals, Sanofi asserted that PBMs were responsible for the exorbitant cost of Mylan's EpiPen, an auto-injector that treats severe allergic reactions. Sanofi explained that Mylan raised the price of EpiPen in order to allow the manufacturer to cut deals with PBMs and other purchasers in exchange for their agreement to give EpiPen preferential treatment or not cover Sanofi's competing product, Auvi-Q. Sanofi also disclosed that it paid Express Scripts $36 million in rebates on an unrelated product in exchange for Express Scripts agreeing to cover Auvi-Q.[72] The differential treatment of these two drugs by these Defendants based on rebates is one example of the *quid pro quo* that affects drug prices and consumers' access to drugs generally, beyond insulin.

106. Prescription drug manufacturers do not seem to be retaining the benefit of (or at least not most of the benefit of) WAC increases. For example, as shown in Figure 5 below, Sanofi disclosed that WAC for its insulins grew 140% from 2012 to 2019, while net prices (*i.e.*, the revenue Sanofi received) declined by 41%.[73] Humira's net versus WAC price, described at Paragraph 104, reflects and demonstrates the same dynamic.

[72] Matthew Perlman, *Sanofi Tells 6th Cir. It Paid $36M To Access EpiPen Market*, Law360 (Jan. 19, 2022), https://www.law360.com/competition/articles/1456660/sanofi-tells-10th-circ-it-paid-36m-to-access-epipen-market.

[73] Adam J. Fein, *Drug Channels News Roundup, March 2020: Sanofi's Gross-to-Net Bubble, Drug Pricing Findings, Amazon Replaces Express Scripts, and Drug Channels Video*, Drug Channels (Mar. 31, 2020), https://www.drugchannels.net/2020/03/drug-channels-news-roundup-march-2020.html.

Figure 5: Sanofi Insulin Prices from 2012–2019



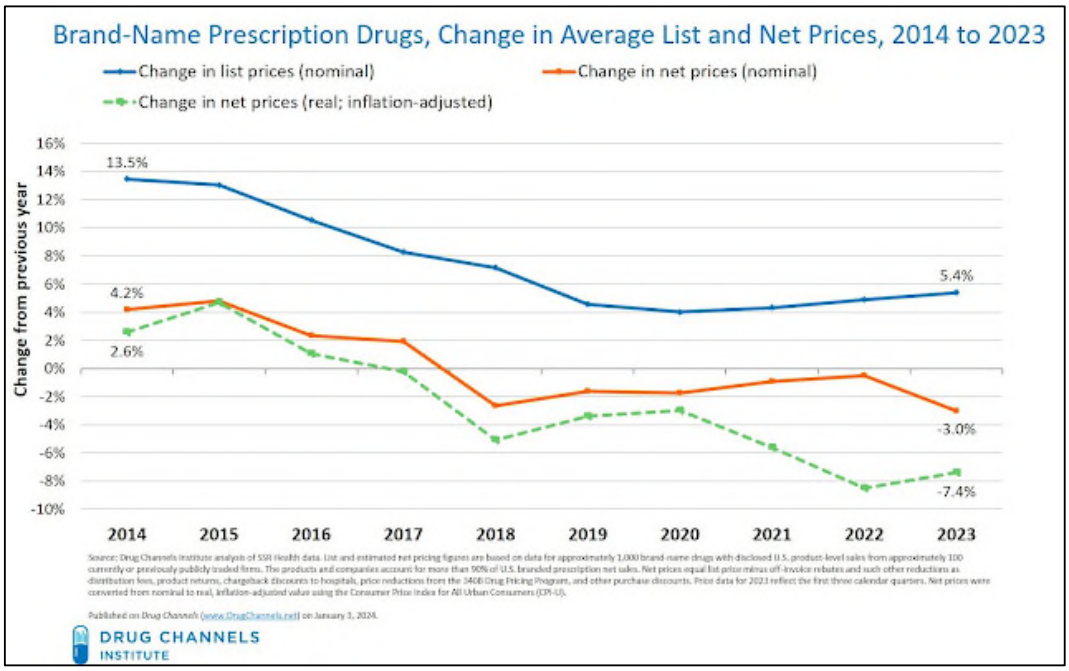
107. In another insulin example, Eli Lilly decided to offer its brand-name insulin product (Humulin) as an authorized generic—a highly unusual move for a drug that is still under patent—because PBMs do not impose rebates on generic drugs.[74] Eli Lilly sold Humulin for $184 with a net revenue of $83.44. In sharp contrast, Eli Lilly sold its authorized generic insulin for $92.50—half the price of its brand-name insulin. Because Eli Lilly's authorized generic has no rebates, there is nothing incentivizing Eli Lilly to inflate the list price. Untethered from rebates, Eli Lilly was able to reduce the price of its product by 50% and make slightly more profit.

108. This artificial price inflation dynamic also exists outside of insulin. In 2023, the list prices for brand-name drugs *increased* by mid-single-digits, yet net prices paid to manufacturers by PBMs after extraction of rebates and fees *decreased* by more than 7% after adjusting for inflation.[75] It was the sixth consecutive year that net prices paid to manufacturers by PBMs for

[74] Weinstein & Schulman, *supra* note 3, at 108.
[75] Adam J. Fein, *Tales of the Unsurprised: U.S. Brand-Name Drug Prices Fell for an Unprecedented Sixth Consecutive Year (And Will Fall Further in 2024)*, Drug Channels (Jan. 3, 2024), https://www.drugchannels.net/2024/01/tales-of-unsurprised-us-brand-name-drug.html.

brand-name drugs decreased. From 2014 to 2023, there were significant gaps between the list prices and net prices of brand-name drugs (*see* Figure 6 below).[76]

Figure 6: Gaps Between List Prices and Net Prices 2014–2023



C. Defendants' Lack of Transparency Allowed Them to Continue Siphoning Off Substantial Portions of Payments from Manufacturers in the Form of Undisclosed Fees

109. Retaining a portion of the rebates they negotiate with manufacturers has historically been a major source of revenue for Defendants. For example, in 2012, approximately 46% of Defendants' revenues were attributable to rebates and price protection fees (additional rebate payments manufacturers are required to pay PBMs if a drug's list price increases beyond an agreed cap).[77]

[76] *Id.*
[77] Percher, *supra* note 63, at 3.

110. Over the past decade, amidst mounting pressure from health benefit plans and the public, Defendants began increasingly passing through rebates. Defendants now tout that they pass through more than 90% of rebates to health benefit plans.[78] But that does not tell the whole story and, in a sleight of hand, distorts the ways in which PBMs continue to drive up prices and their own profits.

111. Even though Defendants are retaining a smaller percentage of rebates, the overall revenue from rebates is increasing: from $46 billion in 2018 to $64 billion in 2022.[79] The gain in overall rebate dollars therefore somewhat offsets the loss in percentage (*i.e.*, 10% of $64 billion is larger than 10% of $46 billion).

112. In addition, Defendants have managed to further increase their profits and avoid passing on payments from manufacturers by recharacterizing these payments from rebates to other fees. Defendants now utilize group purchasing organizations, or GPOs—some of which are offshore corporations—to categorize and recategorize income streams, which allows Defendants to redefine "rebates" and, by extension, avoid their obligation to pass through "rebates." CVS Caremark, Express Scripts, and OptumRx are affiliated with Zinc Health Services LLC (located in the United States), Ascent Health Services LLC (located in Switzerland), and Emisar Pharma Services LLC (located in Ireland), respectively.

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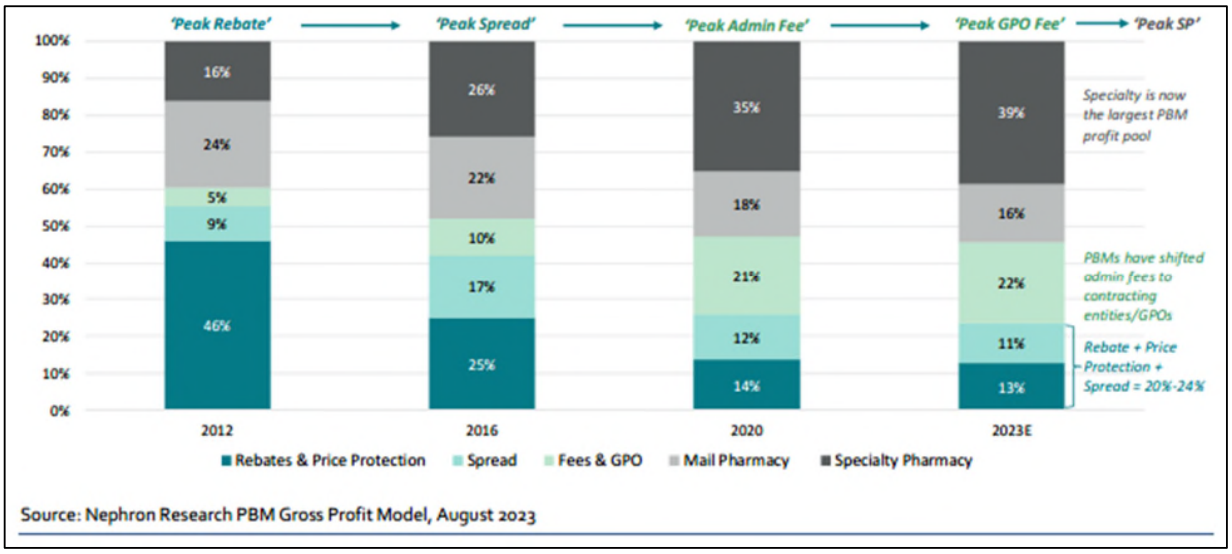
[78] CVS Health, *Improving Access and Lowering Costs*, https://business.caremark.com/content/dam/enterprise/business-caremark/insights/pdfs/2023/PBMFactsheet_Final_06.09.23.pdf (last visited Sept. 4, 2024); Evernorth Health Services, *The Reality of Rebates*, https://www.evernorth.com/esfacts/key-topics/the-reality-of-rebates (last visited Sept. 4, 2024); OptumRx, Inc., *Client and Consumer Support*, https://www.unitedhealthgroup.com/ns/optum-rx/client-and-consumer-support.html (last visited Sept. 5, 2024).

[79] Percher, *supra* note 63, at 6.

113. One 2023 survey looked at PBM compensation from prescription drug manufacturers between 2018 and 2022. It found PBMs' compensation tied to manufacturer fees doubled from $3.8 billion in 2018 to $7.6 billion in 2022.[80] Thus, although increased pass through of rebates to health benefit plans reduced PBMs' traditional sources of profitability, novel PBM fees—including fees manufacturers pay to GPOs—more than offset this decline (as shown in Figure 7 below).[81]

Figure 7: Source of PBM Gross Profits Over Time: A Shift from Rebates and Spread to Fees and Specialty Pharmacy



114. The 2023 Nephron study at Figure 7 found that PBMs shifted administrative fees to their GPOs—adding additional ***non-transparent*** layers to the drug pricing system. These administrative fees increased 56% from $3.8 billion in 2018 to $5.8 billion in 2022. The study further observed the rise of novel fees that manufacturers now pay to GPOs. In 2018, data fees and vendor fees were effectively zero but have since skyrocketed to $969 million and $759 million, respectively. Although it is unclear what some of these new fees represent, data fees are fees for

[80] *Id.* at 2.
[81] *Id.* at 3.

granting manufacturers access to a portal that contains utilization and other data for manufacturers' drugs. Like rebates, administrative, vendor, and data fees are most frequently calculated as a percentage of WAC prices.

115. Defendants' lack of transparency allows them to profit from secret, undisclosed fees that drive up the cost of drugs. It also prevents health benefit plans (and by extension, consumers) from discovering Defendants' unfair and deceptive practices. Defendants' contracts with health benefit plans enable this behavior by restricting access to information, including claim-level data and the gross profits Defendants generate from administering their prescription drug benefits.[82]

116. Seemingly consistent with the data from Nephron's 2023 study, on June 24, 2024, CVS Caremark paid $45 million to the State of Illinois to settle allegations that CVS Caremark failed to disclose and pass through certain payments made to Zinc Health Services LLC that allegedly constitute rebates pursuant to CVS Caremark's contract with Illinois.

IV. WAC Prices for Prescription Drugs Have Skyrocketed Over the Last Couple of Decades, Increasing Prices to Consumers

117. From 2014 to 2020, WAC prices for prescription drugs increased by 33%, outpacing inflation and price increases for any other medical commodity or service.[83]

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[82] Ge Bai, *Policy Options To Help Self-Insured Employers Improve PBM Contracting Efficiency*, Health Affairs (May 29, 2019), https://www.healthaffairs.org/content/forefront/policy-options-help-self-insured-employers-improve-pbm-contracting-efficiency.

[83] Tori Marsh, *Prices for Prescription Drugs Rise Faster Than Prices for Any Other Medical Good or Service*, GoodRx Health (Sept. 17, 2020), https://www.goodrx.com/healthcare-access/drug-cost-and-savings/prescription-drugs-rise-faster-than-medical-goods-or-services; Stephen W. Schondelmeyer & Leigh Purvis, *Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans, 2006 to 2020*, AARP Public Policy Institute (June 2021), at 1, https://www.aarp.org/content/dam/aarp/ppi/2021/06/trends-in-retail-prices-of-brand-name-prescription-drugs-widely-used-by-older-americans.10.26419-2Fppi.00143.001.pdf.

118. Consumers in Puerto Rico are disproportionally harmed by price inflation because even though 70% of the world's best-selling medicines are manufactured in Puerto Rico, that production is exported to the U.S. and imported back into the island, which significantly increases drug costs—meaning consumers in Puerto Rico pay even higher prices than consumers on the mainland.[84]

119. Between 2016 and 2022, there were 1,216 drugs with WAC prices that exceed the rate of inflation (8.5%).[85] The average WAC price increase for these drugs was 31.6%. Some drug prices increased by more than $20,000, or 500%.

120. Rising WAC increases have made life-saving medications unaffordable for many Americans—particularly the elderly. For the average older American taking 4.7 brand-name prescription drugs per month, if drug prices had increased at the rate of general inflation, the annual cash price of therapy in 2020 would have been $13,682 instead of the actual cost of $31,037.[86] This is a significant burden for uninsured consumers or consumers with coinsurance or high-deductible plans.

121. According to a 2019 study, medication insecurity—the inability to pay for prescribed medications—rose 4% from January 2019 to September 2019 (18.9% vs. 22.9%).[87] The study also showed a significant gender gap. In September 2019, medication insecurity affected 27.5% of women compared to 18.1% of men.

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[84] Rosado, *supra* note 62.
[85] Assistant Sec'y for Planning and Evaluation, U.S. Dept. of Health and Human Services, *Price Increases for Prescription Drugs, 2016–2022* (Sept. 30, 2022), at 1, https://aspe.hhs.gov/sites/default/files/documents/e9d5bb190056eb94483b774b53d512b4/price-tracking-brief.pdf.
[86] Schondelmeyer & Purvis, *supra* note 83, at 1.
[87] Dan Witters, *Millions in U.S. Lost Someone Who Couldn't Afford Treatment*, Gallup (Nov. 12, 2019), https://news.gallup.com/poll/268094/millions-lost-someone-couldn-afford-treatment.aspx.

122. Local pharmacists in Puerto Rico report that some medicines that a few years ago cost $3, now cost $300.[88]

123. Insulin—a drug that millions with diabetes need to live—is a prime example of skyrocketing WAC prices. At a century in use, insulin is one of the oldest biologic drugs in modern medicine. In 1999, Humalog (insulin) was affordably priced at approximately $21 per month. Twenty years later, the WAC price had increased by more than 1000% to approximately $332 per month.[89]

124. For a consumer with Type 1 diabetes with commercial insurance, the annual cost of insulin nearly doubled in just a five-year period, from approximately $3,200 in 2012 to $5,900 in 2016.[90]

125. Due to unprecedent pressure on PBMs and insulin manufacturers, insulin costs are now capped at $35 a month for some consumers. Unfortunately, PBMs have not provided this same type of relief for other drugs.

126. Insulin costs are particularly difficult in Puerto Rico, where diabetes is a full-fledged public health epidemic. According to the International Diabetes Federation, more than 20% of Puerto Rico's adult population suffers from diabetes, totaling more than 413,000

[88] Rosado, *supra* note 62.
[89] S. Vincent Rajkumar, *The High Cost of Insulin in the United States: An Urgent Call to Action*, 95 Mayo Clinic Proc. 22, 22 (2020), https://www.mayoclinicproceedings.org/article/S0025-6196(19)31008-0/fulltext.
[90] Jean Fuglesten Biniek & William Johnson, *Spending on Individuals with Type 1 Diabetes and the Role of Rapidly Increasing Insulin Prices*, Health Care Cost Institute (Jan. 21, 2019), https://healthcostinstitute.org/diabetes-and-insulin/spending-on-individuals-with-type-1-diabetes-and-the-role-of-rapidly-increasing-insulin-prices.

individuals altogether.[91] In 2019, diabetes was the second leading cause of death in Puerto Rico.[92] A recent study found that nearly half of Puerto Rico's population has diabetes or pre-diabetes.[93]

V. Defendants' Scheme That Artificially Inflates Drug Prices Is Unfair

127. An unfair practice is one that causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition. *See* 15 U.S.C. § 45(n).

128. An act or practice can cause substantial injury by doing a "small harm to a large number of people or if it raises a significant risk of concrete harm." *F.T.C. v. Neovi, Inc.*, 604 F.3d 1150, 1157–58 (9th Cir. 2010), *as amended* (June 15, 2010). In most cases, a substantial injury involves monetary harm or unwarranted health and safety risks. *LabMD, Inc. v. FTC*, 678 F.App'x. 816, 820 (11th Cir. 2016) (citing FTC, *Policy Statement on Unfairness* (Dec. 17, 1980), https://www.ftc.gov/public-statements/1980/12/ftc-policy-statement-unfairness) (hereinafter "FTC Policy Statement on Unfairness").

129. Defendants' rebate and formulary practices harm a large number of people and raise a significant risk of concrete harm by: (1) increasing consumers' out-of-pocket costs; (2) restricting consumers' access to appropriate and effective prescription drugs; and (3) retaining a significant portion of rebates and other fees thereby shrinking any potential "savings" consumers and or health insurance plans might otherwise provide. They are not outweighed by any countervailing benefits

[91] International Diabetes Federation, *Puerto Rico*, https://idf.org/our-network/regions-members/south-and-central-america/members/90-puerto-rico.html (last updated Apr. 4, 2022).
[92] Institute for Health Metrics and Evaluation, *Puerto Rico*, https://www.healthdata.org/puerto-rico (last visited Nov. 16, 2022).
[93] Marga Parés Arroyo, *Jóvenes puertorriqueñas relatan los retos que sobrellevan para vivir con diabetes*, El Nuevo Día (Nov. 16, 2022), https://www.elnuevodia.com/noticias/locales/notas/jovenes-puertorriquenas-relatan-los-retos-que-sobrellevan-para-vivir-con-diabetes/.

to consumers or to competition. In fact, as explained below, Defendants' rebate and formulary practices tend to negatively affect competitive conditions in the prescription drug market. *See infra* VIII.A.

A. Artificially Inflating WAC Prices Increases Consumers' Out-of-Pocket Costs

130. Defendants' conduct in causing increases in WAC prices increases out-of-pocket costs for uninsured consumers and insured consumers with coinsurance and high deductible plans who are in the deductible phase because their costs are directly tied to the WAC price. This cost increase is not speculative or theoretical; it is guaranteed, because of the connection between consumers' cost-share payment and the WAC price. Thus, when WAC increases, consumers' out-of-pocket costs will increase.

131. For example, when AbbVie raised the WAC price for Humira from $2,914 in 2015 to $5,174 in 2019, consumers with coinsurance (who typically pay around 30% of WAC) saw their out-of-pocket costs for a one-month supply balloon from $874 in 2015 to $1,552 in 2019.[94]

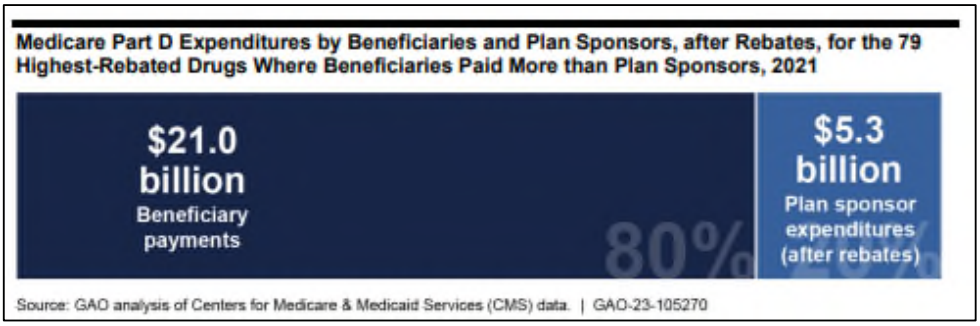
132. Researchers from the University of Southern California found that consumers with coinsurance in Medicare Part D plans had substantially higher out-of-pocket costs for drugs in concentrated markets where the demand for rebates is the highest.[95] In other words, paradoxically, more competitors in the market caused at least certain consumers to pay higher costs, which is contrary to how competitive markets typically work. This can be attributed to the fact that Defendants leverage the availability of competitor drugs to demand higher rebates to give

[94] Gill, *supra* note 14.
[95] Darius Lakdawalla & Meng Li, *Association of Drug Rebates and Competition With Out-of-Pocket Coinsurance in Medicare Part D, 2014 to 2018*, JAMA Network Open (May 5, 2021), at 7, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8100863/.

preferential treatment to one manufacturer's product and exclude others from their formularies. Upon information and belief, the Government believes the same is true for non-Medicare plans.

133. In some instances, consumers are paying proportionately more of the increased drug prices than their health benefit plans. In a 2023 study, the United States Government Accountability Office examined Medicare Part D expenditures by beneficiaries (*i.e.*, consumers) and health benefit plans.[96] It found that payments by beneficiaries increased dramatically for 79 of the 100 drugs receiving the most rebates, demonstrating both the wide scope of rebate-driven price increases and the substantial impact that rebates and price increases have on consumers' out-of-pocket costs.[97] For these 79 drugs, beneficiaries paid $21 billion and health benefit plans paid $5.3 billion (*see* Figure 8 below).[98] In other words, beneficiaries paid approximately 80% of the cost for these 79 drugs while health benefit plans paid only 20% after rebates. Upon information and belief, the same dynamic exists with non-Medicare plans.

Figure 8: Medicare Expenditures by Beneficiaries vs. Health Benefit Plans



134. For consumers with high-deductible plans (or even more modest deductible plans) who are still satisfying their deductibles, consumers pay the full cash price and their health benefit

[96] U.S. Gov't Accountability Office, *Medicare Part D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending* (Sept. 5, 2023), https://www.gao.gov/products/gao-23-105270.
[97] *Id.* at 32–33.
[98] *Id.*

plans pay zero. However, Defendants still receive rebates and other manufacturer fees related to those prescriptions. Thus, they effectively profit from consumers paying the full cash price.

135. In addition to the obvious financial harm, increased out-of-pocket costs create a barrier to treatment. Researchers have found that when drug prices are too high, many consumers will simply not fill their prescriptions.[99] Due in part to high costs, consumers starting new therapy abandoned 98 million prescriptions at pharmacies in 2023 with increasing frequency as out-of-pocket costs rose, with abandonment rates over 55% for prescriptions costing over $250.[100]

136. Insulin is a prime example of the harm caused by drug unaffordability. Defendants know diabetics are rationing their insulin due to cost, which can lead to worse health outcomes. For example, Express Scripts states on its website: "For people with diabetes, medication is essential. . . . [M]issing one dose of any medication can be dangerous for their health and lead to costly and complex outcomes. And yet, the cost of diabetes treatment has led some consumers to make financial sacrifices to afford what they were prescribed, or even ration their medication."[101]

137. One study showed that 20% of Americans with diabetes have rationed their insulin due to financial reasons.[102]

138. The same phenomenon is true locally. Pharmacists in Patillas reported that if medications are not covered by insurance, patients either do not fill them or fill only partial

[99] Arleen Leibowitz et al., *The Demand for Prescription Drugs as a Function of Cost-Sharing* (Oct. 1985) at 18, https://www.rand.org/content/dam/rand/pubs/notes/2005/N2278.pdf.
[100] The IQVIA Institute, *supra* note 66, at 34.
[101] Evernorth Health Services, *Close management of diabetes medications lowers medical costs* (June 15, 2022), https://www.evernorth.com/articles/optimizing-diabetes-care-cost-adherence.
[102] Danielle Ofri, *Even with lawsuits and copay caps, will insulin ever be affordable?*, STAT News (Jan. 20, 2023), https://www.statnews.com/2023/01/20/will-insulin-ever-be-affordable/.

prescriptions due to cost.[103] Economists say that as drug costs increase, some Puerto Rico consumers—mostly elderly and retired consumers—are deciding between medicine and food.[104]

139. In 2020, it was estimated that high out-of-pocket costs for drugs would cause 1.1 million premature deaths of seniors in the Medicare program over the next decade, and lead to an additional $177.4 billion in avoidable Medicare medical costs. Upon information and belief, the effect would be even more acute with respect to non-Medicare plans, where prescription drug benefits are even more limited.

B. Defendants Restrict Consumers' Access to Appropriate and Effective Prescription Drugs

140. Beyond pricing, drug exclusions cause harm and/or raise a significant risk of concrete harm by forcing non-medical switching (altering a consumer's drug therapy for reasons other than a drug's efficacy, side effects, or clinical outcome). In other words, the choice of drugs available to consumers becomes driven not by which drug is safest or most effective for consumers, but by financial side-deals governing whether and at what cost-share amount a drug is placed on Defendants' formulary.

141. In February 2008, CVS Caremark entered into a $38.5 million settlement agreement with 28 State Attorneys General under their consumer protection statutes to resolve allegations that the PBM engaged in deceptive business practices by encouraging doctors to switch consumers

[103] Rosado, *supra* note 62.
[104] Efraín Montalbán Ríos, *Consumidores barajan su presupuesto entre medicamentos y alimentos: Economistas confirman que los residentes de la Isla prefieren gastar más en los servicios de salud que en su canasta básica*, El Vocero (May 12, 2022), https://www.elvocero.com/economia/finanzas/consumidores-barajan-su-presupuesto-entre-medicamentos-y-alimentos/article_8c7404da-742b-11ed-baa0-6bf64d1bf7bf.html.

to different brand-name drugs by saying the consumers or their health benefit plans would save money without disclosing that the drug switching would benefit CVS Caremark.[105]

142. Months later, Express Scripts settled similar allegations with 28 State Attorneys General and the District of Columbia.[106] Among other things, the agreement:

- prohibited Express Scripts from eliciting consumers to switch to drugs that would cost them more;
- prohibited Express Scripts from soliciting drug switches when the originally prescribed drug has a generic equivalent and the proposed drug does not;
- required Express Scripts to inform prescribers of Express Scripts' financial incentives for certain drug switches; and
- required Express Scripts to refrain from making any claims of savings for a drug switch to patients of prescribers unless Express Scripts can substantiate the claims.

143. These changes to address PBM practices that harmed consumers, unfortunately, were short-lived. In the intervening years, Defendants' basic business practices have not changed but have only become more profitable to Defendants, still at consumers' expense. Historically, PBMs excluded medicines with generic equivalents or classes where multiple products have been shown to achieve similar clinical outcomes. Now, Defendants often exclude medicines for

[105] Illinois Attorney General, *Madigan, 28 Attorneys General Reach Settlement with Caremark for Drug Switching Practices* (Feb. 14, 2008), https://www.illinoisattorneygeneral.gov/pressroom/2008_02/20080214.html.
[106] Washington Attorney General, *Attorney General McKenna announces Express Scripts to pay $9.5 million to resolve consumer protection claims* (May 26, 2008), https://www.atg.wa.gov/news/news-releases/attorney-general-mckenna-announces-express-scripts-pay-95-million-resolve.

conditions such as cancer, HIV, and autoimmune disorders, for which variation in patient response to drugs has been well-documented.[107]

144. Defendants have claimed that formulary exclusions only affect a small percentage of consumers. However, each of the Defendants manages prescription drug coverage for tens of millions of consumers, including many Puerto Rico residents.

145. This means that hundreds of thousands of individuals may be forced to switch from their current medication to Defendants' preferred alternative each year. Further, because medications to treat ***chronic*** diseases are among the most frequently targeted by formulary exclusions, vulnerable consumers with chronic illnesses are disproportionately affected, and for much longer periods of time.[108]

146. A 2023 study examining the impact of formulary tier increases on patients' treatment patterns for apixaban, an oral anticoagulant used to prevent strokes in patients with atrial fibrillation, found patients were very reluctant to switch their medication.[109] More than half the patients (57.5%) continued apixaban despite increased out-of-pocket costs ($54 versus $135 for a 30-day supply), 30% discontinued oral anticoagulant treatment, and 12.4% switched to another oral anticoagulant.

147. For consumers with chronic conditions, who often have treatment regimens involving multiple medications that need to work together, having access to their choice of medications can be critical. Frequent changes can be particularly problematic, as changes in one medication can trigger the need for other changes and disrupt treatment.

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[107] Xcenda, *supra* note 49, at 1; *see also* Joyce et al., *supra* note 2, at 396.
[108] Xcenda, *supra* note 49, at 11.
[109] Steven Deitelzweig, *Payer formulary tier increases of apixaban: how patients respond and potential implications*, 39 Current Medical Research & Opinion 1093, 1095 (2023), https://www.tandfonline.com/doi/full/10.1080/03007995.2023.2232636#abstract.

148. Similarly, Defendants increasingly have been excluding drugs approved under the FDA's expedited pathways for novel medicines that meet specific criteria and address unmet medical needs in the treatment of serious and even life-threatening conditions (*e.g.*, Fast Track Designation, Breakthrough Therapy Designation, Accelerated Approval, and Priority Review). In 2022, Defendants each excluded between fourteen to thirty-four products approved through an expedited pathway. This was up sharply from 2016, where Defendants each excluded only one or two products approved through an expedited pathway.

149. Moreover, because each Defendant excludes different medications, and different health benefit plans contract with different Defendants, consumers who change jobs and/or health benefit plans may find their current medications are not covered.

C. Defendants Retain a Significant Portion of Rebates and Other Fees—Shrinking Any Potential "Savings" These Payments Could Provide

150. Defendants claim that rebates and other fees are effective tools in lowering drug prices but fail to disclose that they siphon off much of the purported "savings" these fees seemingly offer.

151. For example, as noted previously, Defendants may argue there is no meaningful difference between a drug with a $50 WAC price and no rebate and a drug with a $100 WAC price and a $50 rebate (or combination of rebate and other fees), because both drugs have the same net price ($50). But that is true only if one ignores the fact that Defendants always retain some portion of the fees they negotiate from manufacturers. If Defendants retain $10 of the $50 rebate or other fees, the $100 drug now has a net price of $60—making it more expensive than the $50 drug with no rebate. In addition, as explained above, many consumers' cost-share amounts are tied to WAC, meaning their out-of-pocket costs will rise along with the WAC price.

152. Moreover, even if Defendants passed through 100% of all payments from manufacturers—which none of them do—consumers whose out-of-pocket costs are tied to WAC prices would still be harmed by the high WAC price/high rebate system that Defendants have engineered. This is because manufacturer payments are passed through to health benefit plans, not to consumers paying inflated cost-share payments.

153. At an April 2019 Congressional hearing on the rising cost of insulin, Novo Nordisk's President acknowledged that the "perverse incentive" in drug pricing harms consumers:

> [T]here is this perverse incentive and misaligned incentives and this encouragement to keep list prices high, and we've been participating in that system because the higher the list price, the higher the rebate. . . . There's a significant demand for rebates. . . . [W]e're spending almost $18 billion a year in rebates, discounts, and fees, and we have people with insurance with diabetes that don't get the benefit of that.[110]

154. At that same hearing, an executive from Sanofi stated: "I think the system became complex and rebates generated through negotiations with PBMs are being used to finance other parts of the healthcare system and not to lower prices to the patient."[111]

VI. Defendants' Deceptive Acts and Practices Mask Their Impact on Drug Pricing and Consumers

155. Defendants' representations that they lower drug costs are demonstrably untrue. As described above, Defendants have engaged in a deceptive and unfair scheme that has the effect of artificially inflating WAC prices to allow Defendants to extract higher rebates and other fees from manufacturers for their own financial benefit to the detriment of consumers. This is the opposite of lowering drug costs.

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[110] *Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin Before the Subcomm. on Oversight and Investigations*, 116th Cong. 86, 88 (2020) (Statement of Doug Langa, President of Novo Nordisk), https://www.congress.gov/event/116th-congress/house-event/LC65499/text?s=q&r=1.

[111] *Id*. at 112 (Statement of Kathleen Tregoning, Executive Vice President for External Affairs of Sanofi).

156. Further, it is deceptive for Defendants to claim that they lower costs, including through the use of rebates and other fees from manufacturers, while failing to disclose that: (1) Defendants' conduct plays a role in artificially inflating WAC prices; (2) a significant portion of WAC prices (*e.g.*, 30% or more) is attributable to rebates and other fees for certain drugs; (3) Defendants profit from rebates and other fees from manufacturers; (4) the high WAC price/high rebate system Defendants engineered will result in some—if not all—consumers paying higher out-of-pocket costs, including consumers with coinsurance (rather than flat copayments) and high deductible plans.

157. Defendants' assertions that their formularies are designed to maximize safety and effectiveness and minimize cost are both unfair and deceptive. As described above, Defendants include and give preferential treatment to certain drugs on their formularies for their own financial benefit, despite the fact that those drugs are less safe or effective or more expensive than competing drugs. Likewise, Defendants exclude drugs that are less expensive or safer or more effective than other drugs based on payments from manufacturers. In other words, Defendants act in their own financial interests, not in the best interests of consumers, who are patients in need of medical treatment who Defendants are obligated to help as intended third-party beneficiaries of Defendants' contracts with the patients' health benefit plans.

158. Further, it is deceptive for Defendants to contend that their formulary decisions are based on scientific evidence and/or cost while failing to disclose that Defendants receive compensation from manufacturers by giving preferential treatment to some drugs and excluding others, and that compensation, rather than (and often in spite of) scientific evidence and/or cost, directs Defendants' formulary decisions.

159. Defendants' formulary decisions will force some consumers to switch medications or potentially ration or forgo treatment because they cannot afford the out-of-pocket costs.

160. Defendants' direct or implied representations that they operate in consumers' best interests while not disclosing their significant conflicts of interests, including the compensation they receive from manufacturers and affiliated pharmacies, is deceptive.

161. Defendants' creation of a system that artificially inflates the price of prescription drugs to allow them to extract increasingly higher rebates while simultaneously representing that they function to lower costs and design formularies to maximize safety, effectiveness, and affordability is a deceptive act or practice.

162. Defendants' deceptive acts and practices mask the impact of their rebate and formulary practices on the market and consumer behavior, making the black box of drug pricing and formulary selection even more difficult to understand, navigate, or change.

VII. Defendants' Deceptive Acts and Practices Are Material to Consumers

163. Defendants' marketing emphasizes their role in and commitment to ensuring that the prescription drugs available to consumers are safe, effective, and affordable because these issues are important to consumers and likely to impact their decision making. Defendants know that, too.

164. For example, CVS Caremark advertises "Your health is our priority[.] As a pharmacy benefit manager (PBM), we manage prescription plans to help make them more cost-effective – so you can get what you need when you need it."[112] It further acknowledges: "Keeping your medication affordable is important."[113] CVS Caremark further claims to "[i]mprov[e] health

[112] CVS Caremark, *About Us*, https://www.caremark.com/about-us.html (last visited Dec. 15, 2024).
[113] CVS Caremark, caremark.com (last visited Dec. 15, 2024).

through affordability" because "people are more likely to take their prescribed medications when they know they can afford them – and that can lead to better health outcomes."[114]

165. For example, Express Scripts claims: "As your pharmacy benefit manager ("PBM"), Express Scripts helps you stress less and save more. We take care of you, so you can focus on what really matters."[115] Express Scripts describes cost as "one of the greatest barriers to care."[116]

166. For example, OptumRx asserts: "Always here for you when you need us – with compassion and care."[117] It further acknowledges: "[M]any people do not take their medications as they should, citing cost as a primary reason."[118] It further states: ""In short, when it comes to treatments for conditions that affect millions of people and drive most employer costs, Optum Rx routinely delivers a far lower price. And lower prices matter."[119]

167. It is also axiomatic that consumers are concerned about the safety and efficacy of prescription drugs. Pricing and access to prescription drugs are also key concerns to consumers.[120] More than 50% of people in the United States are worried about affording prescription drug costs, with larger shares of Black and Hispanic adults and uninsured adults reporting concerns.[121] One

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[114] CVS Health, *Member Affordability*, https://www.cvshealth.com/services/prescription-drug-coverage/member-affordability.html (last visited Dec. 15, 2024).
[115] Express Scripts, Inc., *Pharmacy benefits that benefit you*, https://www.express-scripts.com/pharmacy-benefits-manager (last visited Dec. 15, 2024).
[116] Express Scripts, Inc., *Continually Creating for the Needs of Our Members*, https://www.evernorth.com/who-we-serve/members (last visited Dec. 15, 2024).
[117] OptumRx, Inc., https://www.optumrx.com (last visited Dec. 15, 2024).
[118] OptumRx, Inc., *Experts agree: PBMs add value, lower costs* (Oct. 25, 2023), https://www.optum.com/en/business/insights/pharmacy-care-services/page.hub5.pharmacy-benefit-managers-medication-affordability.html.
[119] *Id.*
[120] Grace Sparks et al., *Public Opinion on Prescription Drugs and Their Prices*, KFF (Oct. 4, 2024), https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/.
[121] *Id.*

quarter of adults have difficulty affording prescription drugs, including larger shares of those who take more medications.[122]

168. The fact that consumers do not directly choose their PBM does not affect the materiality of Defendants' deceptive acts and practices. There are many transactions in which consumers cannot choose their providers. For example, emergency room patients do not choose the hospital to which they are brought by ambulance. Consumers also do not select their mortgage or student loan servicer.

169. Moreover, a health plan may consider complaints made by aggrieved consumers in determining whether to select or retain a particular PBM. In addition, a consumer could change PBMs by selecting a different health plan with a different PBM.

170. Defendants' deceptive acts and practices are also likely to affect consumers' conduct regarding Defendants' services. For example, an insured parent whose allergic child's EpiPen is no longer covered or preferred by one of the Defendants will have to find a different drug for her child. A cancer patient who is required to transition to a different chemotherapy drug because of Defendants' formulary practices will certainly find that information material. Diabetic patients with health plans managed by Defendants decided to ration their insulin in response to Defendants' rebate and formulary practices that increased consumers' out-of-pocket costs. For all these consumers, Defendants' deceptive acts and practices were material because they affected consumers' choice of, or conduct regarding, Defendants' services.

[122] *Id.*

VIII. Defendants Engage in Unfair Methods of Competition

171. Defendants engage in unfair methods of competition that negatively affect competitive conditions in the brand-name prescription drug market and pharmacy market to the detriment of consumers.

A. Defendants' Formulary and Rebate Practices Tend to Negatively Affect Competitive Conditions in the Prescription Drug Market

172. Defendants engage in unfair methods of competition when giving preferential formulary treatment to drugs with the highest rebates when there are multiple drugs in a therapeutic class, which tends to negatively affect competitive conditions among drug manufacturers to the detriment of consumers.

173. Defendants' treatment of biosimilars perfectly illustrates the anti-consumer and anti-competitive incentives Defendants have created. Biosimilars are biologic products that the FDA has approved to be therapeutic substitutes for an existing biologic product because there is no clinically meaningful difference between the biosimilar and the existing biologic product.[123]

174. Biosimilars directly compete with existing biologic products. In general, biosimilars are lower priced than the existing biologic product. One would expect, based on Defendants' marketing statements regarding their roles in the market, that when Defendants are faced with fully interchangeable products with no clinically meaningful differences, Defendants would choose the lowest-priced product. Many times, however, the opposite is true. Often, Defendants put their thumb on the scale in favor of drugs with much higher WAC (list) prices, undeniably for their own financial benefit, and against the interests of their health benefit plan clients and health benefit plan members, giving favored status to drugs that come with higher

[123] Xcenda, *supra* note 49, at 7.

rebates while simultaneously freezing out drugs with considerably lower WAC prices (often biosimilars or generic drugs), thereby causing an artificial distortion of the normal competitive dynamics among drug manufacturers.

175. For example, Viatris (a company formed by the merger between manufacturers Mylan and Upjohn) launched two identical biosimilar insulins that are fully interchangeable with Sanofi's top-selling Lantus. One product is a brand-name biosimilar insulin called Semglee. The other product is a generic biosimilar insulin (Insulin Glargine). Semglee is offered at a WAC 5% below the WAC for Lantus. Insulin Glargine is offered at a WAC 65% lower than the WAC for Lantus. Semglee and Insulin Glargine are the exact same product—the only difference between the two products is price.[124]

176. In their 2022 formularies, none of Defendants gave preferred treatment to the insulin product with the lowest WAC (Insulin Glargine). OptumRx preferred Lantus and excluded Semglee but failed to include Insulin Glargine. Express Scripts preferred the higher-priced biologic (Semglee) and excluded the lower-priced biologic (Insulin Glargine)—even though Semglee and Insulin Glargine are identical. CVS Caremark excluded Lantus and preferred Basaglar—a product that is not even a biosimilar to Lantus—without including Semglee or Insulin Glargine.[125] Because Defendants profit from drugs with higher rebates, they have created a barrier for cheaper biosimilar competitors to enter the market. Moreover, even if all of these products had the same net cost (meaning the brand-name products were the same price as the lower-priced biologic after accounting for rebates), consumers with coinsurance and those enrolled in high-deductible plans

[124] Adam J. Fein, *Why PBMs and Payers Are Embracing Insulin Biosimilars with Higher Prices—And What That Means for Humira*, Drug Channels (Nov. 9, 2021), https://www.drugchannels.net/2021/11/why-pbms-and-payers-are-embracing.html.
[125] *Id.*

would pay greater out-of-pocket costs for the brand-name products than the lower-priced product because their cost-share payments were based on the unrebated prices.

177. Humira biosimilars are another example. Humira biosimilars hit the market in 2023 with WAC prices ranging from 5%-85% below Humira.[126] The net price of Humira was approximately $2,100 compared to less than $1,000 for some of the low WAC price biosimilars.[127] Yet, Defendants continued to give preferential treatment to Humira and refused to cover the biosimilars.[128] The only plausible explanation for favoring a drug that is clinically identical but more expensive than its competitors is that the switch would have cost Defendants in lost rebates and other fees.

178. IQVIA—a healthcare data company—estimated that if Defendants had switched to low WAC biosimilars in 2023, Defendants would have lost 87% in profit from rebates and other fees associated from Humira prescriptions and specialty pharmacies (some of which Defendants own) would have lost 90% profit.[129] By sharp contrast, health benefit plans would have saved 80% in lower drug costs and administrative fees and consumers would have saved 76% on copayments.[130]

179. CVS Caremark announced at the beginning of 2024 that it would remove Humira from its major national commercial formularies and cover Humira biosimilars instead.[131] But there

[126] IQVIA, *Adalimumab Biosimilar Tracking* (Apr. 2, 2024), at 15, https://biosimilarscouncil.org/wp-content/uploads/2024/04/04022024_IQVIA-Humira-Tracking-Executive-Summary.pdf.
[127] *Id*. at 10.
[128] *Id*. at 5–6.
[129] *Id*. at 13.
[130] *Id*.
[131] CVS Health, *CVS Caremark accelerates biosimilars adoption through formulary changes* (Jan. 3, 2024), https://www.cvshealth.com/news/pbm/cvs-caremark-accelerates-biosimilars-adoption-through-formulary-changes.html.

was a catch. CVS Caremark gave preferential formulary treatment to a mix of high and low WAC price biosimilars, including biosimilars manufactured by Cordavis—a subsidiary of CVS Health, which also operates CVS Caremark.[132]

180. Similarly, Express Scripts announced in August 2024 that it would also remove Humira from its 2025 commercial formulary in favor of multiple biosimilars with a mix of high and low WAC prices, including biosimilars manufactured by Quallent Pharmaceuticals—a subsidiary of Evernorth, which also owns Express Scripts.[133]

181. In other words, CVS Caremark and Express Scripts favored the higher priced, higher rebated Humira and systematically excluded lower priced biosimilar products until they began making their own lower priced biosimilar products from which they could profit.

182. Defendants also stymied biosimilars for Remicade—another blockbuster autoimmune drug used to treat many chronic diseases, such as rheumatoid arthritis, plaque psoriasis, and Crohn's disease. Pfizer launched a biosimilar called Inflectra at a 15% discount to Remicade and then later at a 35% discount to Remicade.[134] But Defendants initially excluded Inflectra in favor of Remicade, presumably because Remicade had a higher WAC price and a higher rebate. By the end of the second quarter in 2017, Inflectra had generated sales of just $40 million in the United States compared to sales of $2.2 billion of Remicade.[135]

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[132] Adam J. Fein, *Humira Biosimilar Price War Update, Should We Be Glad that CVS Health and Express Scripts Are Using Private Label Products to Pop the Gross-to-Net Bubble?* (Sept. 4, 2024), https://www.drugchannels.net/2024/09/humira-biosimilar-price-war-update.html.
[133] *Id*.
[134] Eric Sagonowsky, *With its Remicade biosimilar stymied by the brand, Pfizer sued Johnson & Johnson for 'anticompetitive' dealmaking*, Fierce Pharma (Sept. 20, 2017), https://www.fiercepharma.com/legal/tired-its-biosim-being-stiff-armed-pfizer-files-suit-over-j-j-s-remicade-contracting.
[135] Kevin Dunleavy, *Pfizer, Johnson & Johnson settle high-profile Remicade biosim lawsuit on undisclosed terms*, Fierce Pharma (July 26, 2021),

183. Forcing manufacturers to compete based on the kickbacks they pay to Defendants is an unfair method of competition because it undermines competition on the merits, which, for prescription drugs, is their safety, efficacy, or price. Instead, it constrains products available to consumers and increases prices paid by consumers without regard to the quality, safety, or desirability of the product to consumers—but solely on the willingness and ability of the product manufacturer to offer quid pro quo rebates and other fees to Defendants to gain access to their formularies.

184. Defendants' conduct is coercive, exploitative, and restrictive because it incentivizes manufacturers to compete for formulary placement by prioritizing rebates over the true lowest net price or the safety or efficacy of their products as explained in Paragraphs 74-128 and 174-186. It also exploits and abuses vulnerable consumers by denying them access to certain medications, including safer and more affordable and effective medications, and forcing certain consumers to pay inflated cost-share payments as explained in Paragraphs 142-151 and 132-141, respectively.

B. Defendants Impose Unfair Contractual Terms on Independent Pharmacies That Negatively Affect Competition and Consumers

185. A pharmacy's access to Defendants' networks is critical for financial survival. Given that Defendants collectively control 80% of the PBM market nationally, being out of network with just one of the Defendants and being unable to bill that Defendant for drug claims would render it financially unviable for a pharmacy to operate. Thus, many pharmacies—particularly independent pharmacies—have virtually no option but to accede to take-it-or-leave-it contractual terms that Defendants impose in order to be included in their networks.

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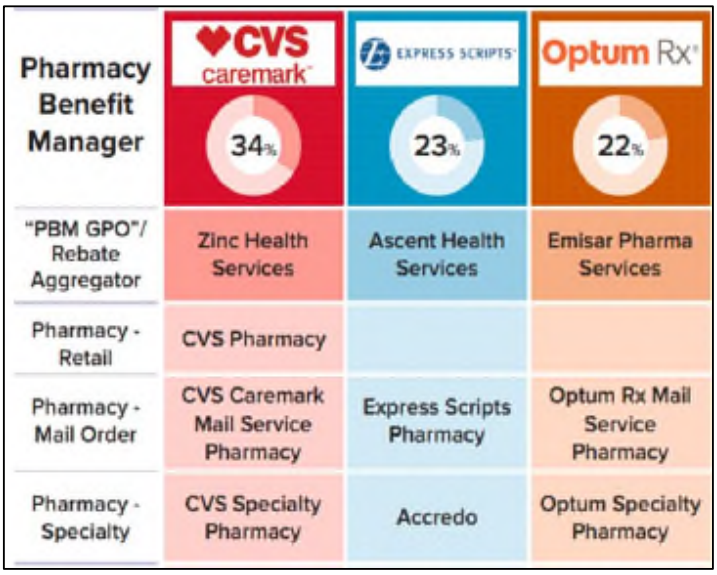
https://www.fiercepharma.com/pharma/pfizer-johnson-johnson-agree-to-a-settlement-terms-undisclosed-biosimilar-lawsuit.

186. In addition, Defendants own or are otherwise affiliated with various pharmacies (*see* Figure 9 below).[136] This means Defendants are in competition with many of the non-affiliated pharmacies they contract with as network pharmacies. As laid out below, Defendants have steered consumers to their own pharmacies or offered higher payments to their own pharmacies, at the expense of independent pharmacies that depend on access to their networks to remain afloat.

Figure 9: Defendants' Ownership and Vertical Integration



187. As described below, Defendants have abused their market power by forcing unfair contractual terms on independent pharmacies that tend to negatively affect competitive conditions in the pharmacy market and negatively impact consumers.

188. Independent pharmacies, which are critical and trusted members of many communities, are going out of business across the country. Douglas Hoey from the National Community Pharmacists Association predicted: "Nearly a third of independent pharmacy owners

[136] Staff of U.S. Federal Trade Comm'n, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (July 2024) at 6 (modified version of chart), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf (hereinafter "FTC PBM Report").

may close their stores this year under pressure from plunging prescription reimbursements by big insurance plans and their pharmacy benefit managers."[137] The same is true in Puerto Rico, where independent pharmacies struggle to keep their doors open. These closures contribute to the growth of pharmacy deserts, which are low-access communities where residents must travel farther to get to the nearest pharmacy to fill their prescriptions.[138]

189. Many consumers have developed relationships with their local, community pharmacists. If local, independent pharmacies go out of business, consumers will have little choice but to use large, chain pharmacies, whose understaffing and volume requirements have resulted in serious medication errors.[139] The closing of independent pharmacies also threatens convenient access for consumers in more rural areas of the island, which depend upon independent pharmacies for access to prescription drugs and other services.

1. Defendants Pay Low Reimbursement Rates—Sometimes Below Pharmacies' Acquisition Costs

190. Pharmacies receive reimbursements for filling prescriptions in two common ways. First, the primary revenue source is the "PBM-to-pharmacy spread" or difference between what it costs the pharmacy to acquire the drug from a wholesaler and the reimbursement from the PBM when an insured consumer fills a prescription. Second, some contracts include a dispensing fee to help cover the pharmacy's overhead.

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[137] National Community Pharmacists Association, *Local Pharmacies on the Brink, New Survey Reveals* (Feb. 27, 2024), https://ncpa.org/newsroom/news-releases/2024/02/27/local-pharmacies-brink-new-survey-reveals.

[138] Noelle Kwan, *The Impact of Pharmacy Deserts*, U.S. Pharmacist (April 2024) at 33, https://bt.e-ditionsbyfry.com/publication/?i=819035&p=46&view=issueViewer.

[139] Ellen Gabler, *How Chaos at Chain Pharmacies Is Putting Patients at Risk*, N.Y. Times (Oct. 13, 2021), https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html.

191. Defendants also profit from the spread between the amount health benefit plans agree to pay Defendants for prescription drugs and the amount Defendants reimburse pharmacies to fill prescriptions (the "PBM-to-health benefit plan spread"). The lower the reimbursement rate Defendants can negotiate with pharmacies, the greater Defendants' profits.

192. In July 2024, the Federal Trade Commission ("FTC") released an interim report titled: "Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies." It concluded that increased concentration in the PBM market may give the leading PBMs, including Defendants, the leverage to enter into complex and opaque contractual relationships that disadvantage many independent pharmacies and the consumers they serve. [140]

193. In the first instance, these contracts, including Defendants', do not inform pharmacies what their reimbursements will be prior to filling prescriptions. After the prescription is filled, pharmacies submit claims through the relevant PBM's claims adjudication system and are later reimbursed by the PBM (minus any cost-share payment made by consumers when they pick up their prescription).

194. Defendants typically calculate reimbursements to pharmacies based on a discount off the lowest potential price, which is often the Maximum Allowable Cost ("MAC") (*i.e.*, Defendants' own proprietary pricing benchmark for generic drugs).[141] For example, Defendants' contract with a pharmacy may specify that the pharmacy will be reimbursed MAC minus X%, or some pre-set discount from the price set by Defendants.[142] These prices often do not reflect the

[140] FTC PBM Report, *supra* note 136, at 3.
[141] Three Axis Advisors, *Unraveling the Drug Pricing Blame Game*, at 40 (Sept. 2023), at 2, https://static1.squarespace.com/static/5c326d5596e76f58ee234632/t/650924780b6b9c590edfa2b4/1695097983750/Unravelling_the_Drug_Pricing_Blame_Game_3AA_APCI_0923.pdf.
[142] FTC PBM Report, *supra* note 136, at 58–59.

actual price at which pharmacies acquire drugs. Some reimbursements are even below the pharmacies' acquisition costs—meaning pharmacies lose money when they fill the prescriptions.

195. MAC prices are specific to generic drugs, which account for approximately 91% of prescriptions filled in the United States. Defendants maintain "MAC lists" which are proprietary price lists that Defendants create, maintain, and continuously update, sometimes on a weekly basis or even more frequently. The lists are supposedly tied to acquisition costs meant to encourage pharmacies to source drugs from low-cost suppliers. But Defendants create different MAC lists for different clients. The FTC found vast disparities between how many lists each PBM, including Defendants, maintains, with one having tens of thousands of lists, while others have under 200. Defendants are also quick to update MAC lists when acquisition costs decrease and slow to update MAC lists when acquisition costs increase.

196. According to the 2024 FTC PBM Report, pharmacies are often not even allowed to see the MAC list nor to understand how they are set. Further, pharmacies are not notified when Defendants update their pricing lists, making it difficult for pharmacies to question or challenge the lists. It can also be cost prohibitive for pharmacies to challenge the ultimate reimbursements. Even if they do, the process is typically controlled by Defendants and therefore hardly impartial.

197. In Georgia, the American Pharmacy Cooperative, which represents independent pharmacies, reviewed the prices an independent pharmacy was reimbursed for certain prescriptions compared to nearby chain pharmacies. The chain pharmacies received an average of $54 for filling the antidepressant bupropion, but the independent pharmacy only received $5.54.[143]

[143] Andy Miller, *PBM Math: Big Chains Are Paid $23.55 To Fill a Blood Pressure Rx. Small Drugstores? $1.51*, KFF Health News (Oct. 24, 2024), https://kffhealthnews.org/news/article/pbm-pharmacy-benefit-managers-independent-drugstores-versus-big-chain-prices/.

Similarly, for the blood pressure medicine amlodipine, the chain pharmacies were paid an average of $23.55, while the independent pharmacy was paid $1.51.[144] The same incentives apply to Defendants' pharmacy reimbursement practices nationally and, upon information and belief, they result in similar disparities in the payments to independent pharmacies in Puerto Rico.

198. The Mississippi Board of Pharmacy uncovered similar conduct in an audit of OptumRx. It identified over 75,000 instances in which OptumRx reimbursed its affiliated pharmacies at higher rates than its unaffiliated pharmacies for the same prescriptions drugs.[145] It also found that OptumRx used 49 different MAC lists, including 15 MAC lists exclusive to independent pharmacies and 22 MAC lists solely for chain pharmacies. These lists showed OptumRx reimbursed independent pharmacies at rates 74% lower than chain pharmacies on average. Even worse, the Mississippi Board of Pharmacy found consumers were almost twice as likely to pay the full cost of prescription drug claims without contributions from their health benefit plans at independent pharmacies than at affiliated pharmacies.

199. In response to concerns over excessive PBM-to-pharmacy spreads and financial viability of independent pharmacies, the West Virginia Medicaid program adopted a new pricing methodology in 2017 that requires PBMs to reimburse pharmacies no less than the National Average Drug Acquisition Cost ("NADAC"), a common measure of pharmacy acquisition cost of drugs based on amounts reported to the Centers for Medicare & Medicaid Services by pharmacies,

[144] *Id*.
[145] Gwen Dilworth, *Optum audit shows possible law violation, lower payments to independent pharmacies*, Mississippi Today (Nov. 7, 2024), https://www.djournal.com/mississippi-today/optum-audit-shows-possible-law-violation-lower-payments-to-independent-pharmacies/article_54966fd0-9d5a-11ef-bed5-83f21fb6e2dd.html.

plus a professional dispensing fee of $10.49 per prescription.[146] This change essentially replaced PBMs' traditional black-box with a more transparent approach. West Virginia estimated this change saved its Medicaid program over $54 million in one year despite an increase in total pharmacy reimbursement and higher volume of prescriptions.[147] The greater price transparency had driven down PBMs' excessive PBM-to-pharmacy spreads that had been maintained at the expense of pharmacies.[148]

200. Compounding the already thin or negative margins for dispensing drugs based on Defendants' reimbursements, Defendants require or incentivize consumers to fill 90-day instead of 30-day prescriptions by waiving or reducing consumers' out-of-pocket cost for longer prescriptions. This practice disadvantages pharmacies because instead of receiving three dispensing fees to fill three, 30-day prescriptions, pharmacies only receive one dispensing fee. The American Psychiatric Association has also expressed concerns about CVS pharmacies' practice of ignoring explicit instructions to dispense limited amounts of medication to mental health patients because it may inadvertently lead more patients to attempt suicide by overdosing.[149]

2. Defendants Steer Consumers to Their Own Affiliated Pharmacies—Particularly for Specialty Drugs

201. Defendants further disadvantage independent pharmacies and consumers by driving more profitable business—including filling prescriptions for high cost specialty drugs (explained in more detail below)—to their own pharmacies.

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[146] Navigant, *Pharmacy Savings Report: West Virginia Medicaid* (Apr. 2, 2019) at 12–13, https://dhhr.wv.gov/bms/News/Documents/WV%20BMS%20Rx%20Savings%20Report%20201 9-04-02%20-%20FINAL.pdf.
[147] *Id*. at 5.
[148] *Id*.
[149] Gabler, *supra* note 139

202. Pharmacies dispense prescriptions through two main formats—retail pharmacies (*i.e.*, brick and mortar) and mail order pharmacies. There is also a rapidly expanding pharmacy segment called specialty pharmacies, which can be retail or mail order pharmacies, that dispense specialty drugs.

203. Defendants' contracts prohibit their non-affiliated network pharmacies from providing mail order services. Thus, in the mail order market, Defendants face little to no competition.

204. Specialty drugs account for a significant portion of drug expenditures. Express Scripts stated that "[e]ven though less than 2% of the population uses specialty drugs, those prescriptions account for a staggering 51% of total pharmacy spending."[150]

205. In addition, more than 60% of all specialty drugs (by revenue) are dispensed by the specialty pharmacies affiliated with Defendants. This is not the product of consumer choice or those pharmacies providing better prices or services; rather, it is the product of Defendants forcing consumers to use their affiliated pharmacies.

206. Defendants steer certain medications to their affiliated pharmacies by expanding the definition of "specialty drugs" which triggers special exclusivity provisions in Defendants' contracts with certain health benefit plans. Per these provisions, specialty drugs can only be filled by Defendants' own specialty pharmacies. There is no standard definition of "specialty drugs" and Defendants are mostly free to make their own determinations and have used this flexibility to steer higher cost and higher margin prescriptions to be filled by their own specialty pharmacies.

[150] *How PBMs distort and undertime specialty drug pricing guarantees*, 46brooklyn (May 10, 2023), https://www.46brooklyn.com/research/2023/5/10/how-pbms-distort-and-undermine-specialty-drug-pricing-guarantees-blac.

207. The FTC analyzed the number of specialty drug designations by PBM for five PBMs (described as PBMs A through E), including Defendants. It found all PBMs increased the overall number of drugs on their specialty drug lists and that drugs were treated differently among the different PBMs, suggesting that it was business practices, not qualities intrinsic to these drugs or their dispensing that drove treatment as a specialty drug. For example, PBM A increased its designations of specialty generics by 268% from 2017 to 2021; however, PBM E only increased its designations of specialty generics by 19% during the same time period (*see* Figure 10 below showing the increase of specialty drug designations for specialty brand drugs and specialty generic drugs among the five PBMs the FTC studied from 2017 to 2021).[151]

Figure 10: Growth and Mix of Specialty Drugs Covered by PBMs for Commercial Members, 2017–2021

	Growth in Number of Drugs Covered, 2017-2021		Specialty Generic As Percent of Total, 2021
	Specialty Brand	Specialty Generic	
PBM A	70%	268%	13%
PBM B	44%	233%	11%
PBM C	41%	94%	13%
PBM D	31%	73%	15%
PBM E	20%	19%	15%

208. One recent study found that only 32% of specialty drugs were included on all Defendants' specialty drug lists and 23% were included on two of their lists. The remaining 45% of specialty drugs were unique to a single Defendant.[152] This variability in these designations

[151] FTC PBM Report, *supra* note 136, at 38.
[152] *Id*. at 37–39 (citing Adam J. Fein, Drug Channels Inst., *The 2024 Economic Drug Report on U.S. Pharmacies and Pharmacy Benefit Managers* (Mar. 2024), at 24, https://drugchannelsinstitute.com/files/2024-PharmacyPBM-DCI-Overview.pdf).

supports that the designations are based on Defendants' subjective determinations rather than any scientific reasoning or objective measure.

209. Designating a drug as a specialty drug without good cause is particularly harmful to consumers because consumers have higher cost-share payments for specialty drugs. For example, in 2024, some health benefit plans with separate tiers for specialty drugs charged an average copayment of $118 for specialty drugs compared to an average copayment of $12–$65 depending on whether the drug is a generic drug or a preferred or non-preferred brand-name drug.[153]

210. Such steering tactics eliminate competition from the marketplace, ultimately harming consumers in terms of cost, service, and convenience. For example, Defendants often require consumers to utilize their specialty pharmacies for drugs administered in clinical settings, such as chemotherapy. In some instances, consumers are forced to obtain needed drugs from Defendants' specialty pharmacies and bring the drugs with them to receive treatment, a practice known as "brown bagging." Or, they may have to purchase their drug from Defendants' specialty pharmacies and have it shipped to their doctors' offices, a practice known as "white bagging." The American Society of Clinical Oncology opposes "brown bagging," and has expressed concerns about "white bagging," because the practices remove doctors' ability to ensure the safe preparation and handling of drugs.[154]

[153] Claxton et al., *supra* note 13, at 158, 154.
[154] American Soc'y of Clinical Oncology, *"Brown Bagging" and "White Bagging" of Chemotherapy Drugs* (2021), www.asco.org/files/content-files/advocacy-and-policy/documents/2021-White-Brown-Bagging-Update.pdf.

211. According to a 2023 survey on PBM compensation, fees from specialty pharmacies have become a primary source of revenue for PBMs—accounting for an estimated 39% of their revenue.[155]

212. The FTC also found that Defendants are often reimbursing their own pharmacies significantly more than unaffiliated pharmacies for filling specialty medications. The FTC compared gross reimbursement rates paid by Defendants with rates paid to unaffiliated pharmacies and to the NADAC. Defendants' affiliated pharmacies received reimbursements often roughly 20- to 40-times higher than NADAC. For example, in 2022, Defendants reimbursed affiliated pharmacies for generic Zytiga (used to treat prostate cancer) more than $5,800 per month—25-times the $229 acquisition cost reflected by NADAC. These high costs ultimately are passed on to consumers and health benefit plans.

213. When an affiliated pharmacy is a consumer's only choice, that pharmacy has no incentive to provide competitive prices or better services. Consumers often experience frustration when dealing with affiliated specialty pharmacies—missed deliveries, medications that are spoiled through improper handling, etc.—that undermine their care and create health risks. Moreover, as noted above, consumers who have developed a trusted relationship with a community pharmacist can find that provider relationship disrupted when Defendants force them to get their specialty medication from a stranger.

214. Defendants' use of their enormous market power to force independent pharmacies to accept low reimbursement rates, including rates that are sometimes below pharmacies' acquisition costs—and then steer more profitable business to Defendants' own affiliated pharmacies—particularly for specialty drugs—negatively impacts independent pharmacies'

[155] Percher, *supra* note 63, at 3.

ability to compete in the pharmacy market and provide services to consumers. This dysfunctional market has made independent pharmacies a dying industry. It also grants Defendants a monopoly in the specialty drug market, allowing Defendants to charge noncompetitive prices, which negatively impacts consumers.

215. As a result of each and every unfair, deceptive, and anti-competitive act and practice described above, Defendants have obtained financial benefits from consumers and independent pharmacies that it would be inequitable and unjust for Defendants to retain.

CLAIMS FOR RELIEF

COUNT ONE
Violation of the Fair Competition Act 10 L.P.R.A. § 259
Deceptive Acts and Practices

216. The Government re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

217. 10 L.P.R.A. § 259 prohibits deceptive acts or practices in trade or commerce.

218. Although Section 259 does not define "deceptive acts or practices," the FTC has interpreted the term deception under the analogous Section 5 of the FTC Act to be "a representation, omission or practice that is likely to mislead the consumer." *See* FTC Policy Statement on Deception at 2 ("FTC Deception Statement"), appended to *In re Cliffdale Assocs., Inc.*, 103 F.T.C. 110, 174 (F.T.C. 1984).

219. A 'material' misrepresentation or practice is one which is likely to affect a consumer's choice of or conduct regarding a product. *Id.* at 5.

220. Defendants engage in trade and commerce by administering prescription drug benefits for Puerto Rico consumers as described in Paragraphs 54–63.

221. Since in or around 2012, if not earlier, Defendants have engaged in deceptive acts or practices in trade or commerce in violation of 10 L.P.R.A. § 259 by, among other things:

a. misrepresenting that Defendants function to lower the cost of prescription drugs, including through the use of rebates and other fees from manufacturers, as described in Paragraphs 64–73 and 157–164;

b. representing that Defendants function to lower prescription drug costs, including through the use of rebates and other fees from manufacturers, while failing to disclose that, among other things:

i. Defendants' practices artificially inflate WAC prices for brand-name prescription drugs as described in Paragraphs 64–73 and 157–164;

ii. a significant portion of WAC prices (*e.g.*, 30% or more) are attributable to rebates and other fees from manufacturers as described in Paragraphs 64–73 and 157–164;

iii. Defendants profit from rebates and other fees from manufacturers as described in Paragraphs 64–73 and 157–164;

iv. the high WAC price/high rebate system Defendants engineered will result in a substantial number of consumers paying higher out-of-pocket costs as described in Paragraphs 64–73 and 157–164.

c. misrepresenting that Defendants design their formularies to maximize safety and effectiveness and minimize costs as described in Paragraphs 64–73 and 157–164;

d. representing that Defendants design their formularies to maximize safety and effectiveness and minimize costs while failing to disclose that:

i. Defendants may receive more compensation from manufacturers by preferring or excluding certain drugs as described in Paragraphs 64–73 and 157–164; and/or

ii. even if Defendants cover or prefer drugs with the lowest net cost (*i.e.*, WAC prices minus rebates or other price concessions from manufacturers), those drugs may not result in the lowest out-of-pocket cost for consumers as described in Paragraphs 64–73 and 157–164;

e. representing, directly or by implication, that Defendants operate in consumers' best interests while not disclosing Defendants' significant conflicts of interest, including the compensation Defendants receive from manufacturers and affiliated pharmacies as described in Paragraphs 64–73 and 157–164;

f. representing that Defendants retain a specified percentage of rebates without disclosing that Defendants receive many other sources of compensation from manufacturers, including compensation that—like rebates—is based on a percentage of WAC prices as described in Paragraphs 64–73 and 157–164;

g. engaging in practices that artificially inflate the price of brand-name prescription drugs while representing that Defendants function to lower prescription drug prices as described in Paragraphs 64–73 and 157–164;

h. preferring drugs on Defendants' formularies that are less effective, safe, and/or affordable than other drugs for their own financial benefit while representing Defendants design their formularies to maximize safety and effectiveness and minimize costs as described in Paragraphs 64–73 and 157–164; and/or

i. engaging in self-dealing practices in negotiations with manufacturers and pharmacies that negatively impact consumers while representing Defendants are working for the benefit of consumers as described in Paragraphs 64–73 and 157–164.

222. Upon information and belief, the Government believes Defendants' conduct is ongoing.

223. Defendants' misrepresentations and omissions were material and were likely to mislead consumers for the reasons stated in Paragraphs 165–172.

224. Defendants' express misrepresentations are also presumptively material because they relate to matters of consumer-patients' health and safety. As the Supreme Court of the United States has stated, "[i]n the absence of factors that would distort the decision to advertise, we may assume that the willingness of a business to promote its products reflects a belief that consumers are interested in the advertising." *Cent. Hudson Gas & Elec. Co. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 567–68 (1980).

225. Defendants' deceptive practices constitute multiple violations of 10 L.P.R.A. § 259.

COUNT TWO
Violation of the Fair Competition Act 10 L.P.R.A. § 259
Unfair Acts and Practices

226. The Government re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

227. 10 L.P.R.A. § 259 prohibits unfair acts or practices in trade or commerce.

228. Although Section 259 does not define "unfair acts or practices," the FTC defines an unfair practice to be one that "causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition." 15 U.S.C. § 45(n).

229. An act or practice can cause substantial injury by doing a "small harm to a large number of people or if it raises a significant risk of concrete harm." *Neovi, Inc.*, 604 F.3d at 1157–58. In most cases, a substantial injury involves monetary harm or unwarranted health and safety risks. *LabMD, Inc.* 678 F.App'x. at 820.

230. Defendants engage in trade and commerce by administering prescription drug benefits for Puerto Rico consumers as described in Paragraphs 54–63.

231. Since in or around 2012, if not earlier, Defendants have engaged in unfair acts or practices in trade or commerce in violation of 10 L.P.R.A. § 259 by engaging in a scheme to artificially inflate WAC prices for brand-name prescription drugs to allow Defendants to extract higher fees as explained in Paragraphs 74–118.

232. Defendants' scheme to artificially inflate WAC prices for brand-name prescription drugs is unfair because it causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition as explained in Paragraphs 129–156.

233. Upon information and belief, the Government believes Defendants' conduct is ongoing.

COUNT THREE
Violation of the Fair Competition Act 10 L.P.R.A. 268(b)
Government Damages

234. The Government re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

235. Pursuant to 10 L.P.R.A. § 268, Puerto Rico may sue to recover damages caused by any person that engages in the unfair and deceptive acts and practices declared unlawful by the provisions of this chapter.

236. Defendants are "persons" under 10 L.P.R.A. § 257 because they are corporations.

237. As described above, since in or around 2012, if not earlier, Defendants have engaged in an unfair and deceptive scheme to artificially inflate WAC prices for brand-name prescription drugs to allow Defendants to extract higher fees as explained in Paragraphs 64–118 and 129–172. This scheme ultimately resulted in artificially inflated prices across the market because WAC prices remain constant regardless of who is purchasing that product.

238. The Government did not contract with Defendants in this action but was still forced to pay inflated prices for prescription drugs as a result of Defendants' illegal scheme that resulted in artificially inflated prices for prescription drugs.

239. Defendants' unlawful conduct thus damaged the Government by increasing the price the Government paid for prescription drugs.

240. Upon information and belief, the Government believes Defendants' conduct is ongoing.

COUNT FOUR
Violation of the Fair Competition Act 10 L.P.R.A. § 259
Unfair Methods of Competition

241. The Government re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

242. 10 L.P.R.A. § 259 prohibits unfair methods of competition in trade or commerce.

243. Defendants engage in trade and commerce by administering prescription drug benefits for Puerto Rico consumers as described in Paragraphs 54–63.

244. According to the Federal Trade Commission, a method of competition is unfair if it goes beyond competition on the merits.[156] A method of competition is conduct undertaken by an actor in the marketplace—as opposed to merely a condition of the marketplace, not of the actor's making, such as high concentration or barriers to entry.[157] Competition on the merits (which is not unfair) may include, for example, superior products or services, superior business acumen, truthful marketing and advertising practices, investment in research and development that leads to innovative outputs, or attracting employees and workers through offering of better employment terms.[158]

245. When evaluating whether conduct goes beyond competition on the merits there are two key criteria to consider. First, the conduct may be coercive, exploitative, collusive, abusive, deceptive, predatory, or involve the use of economic power of a similar nature. It may also be restrictive or exclusionary, depending on the circumstances. Second, the conduct must tend to negatively affect competitive conditions, including, for example, conduct that tends to foreclose

[156] *See* Federal Trade Commission, *Policy Statement Regarding the Scope of Unfair Methods of Competition Under Section 5 of the Federal Trade Commission Act* (Nov. 10, 2022) at 8–9, https://www.ftc.gov/system/files/ftc_gov/pdf/P221202Section5PolicyStatement.pdf.
[157] *Id*. at 8.
[158] *Id*. at 8–9.

or impair the opportunities of market participants, reduce competition among rivals, limit choice, or otherwise harm consumers. These two principles are weighed according to a sliding scale.

246. Examples of unfair competition includes, but is not limited to: (1) a manufacturer's use of its economic power over its dealers to coerce them into buying tires, batteries, or accessories only from those who paid the manufacturer a commission, *FTC v. Texaco, Inc.*, 393 U.S. 223, 229–230 (1968); *Atlantic Refining Co. v. FTC*, 381 U.S. 357, 371 (1965); (2) offering special benefits to dealers who agreed to exclude competing product lines, *FTC v. Brown Shoe Co.*, 384 U.S. 316. 319–20 (1966); (3) scheming to control prices by cutting off supplies to those selling at a discount, *FTC v. Beech-Nut Packing Co.*, 257 U.S. 441, 455 (1922), (4) participating in collective action to eliminate price competition, *FTC v. National Lead Co.*, 352 U.S. 419, 429–30 (1957), *FTC v. Cement Institute*, 333 U.S. 683, 725–26 (1948), *Sugar Institute, Inc. v. United States*, 297 U.S. 553, 597–600 (1935), (5) marketing inferior goods to children through use of a gambling scheme, *FTC v. R.F. Keppel & Bro., Inc.*, 291 U.S. 304, 314 (1934), (6) or inducing use of exclusive dealing contracts that are restrictive in character, *FTC v. Motion Picture Advertising Service Co.*, 344 U.S. 392, 396–98 (1953).

PBM Defendants' Formulary and Rebate Practices

247. PBM Defendants engage in unfair methods of competition when giving preferential treatment to drugs with the highest rebates when there are multiple drugs in a therapeutic class as explained in Paragraphs 174–186. This method of competition is unfair because it goes beyond competition on the merits.

248. PBM Defendants' conduct is coercive, exploitative, collusive, abusive, deceptive, predatory, and restrictive, and exclusionary because they use their enormous market power to: (1) induce rival manufacturers to compete for formulary placement by prioritizing rebates over lower

WAC prices or net prices or the safety or efficacy of their products as explained in Paragraphs 74–118 and 174–186; and (2) exploit and abuse vulnerable consumers by denying them access to certain medication, including more affordable medications, and force certain consumers to pay inflated cost-share payments as explained in Paragraphs 142–151 and 132–141, respectively.

249. PBM Defendants' conduct tends to negatively affect competitive conditions because it: (1) incentivizes drug manufacturers to compete for formulary placement by inflating WAC prices to counteract high rebates and other fees and deters drug manufacturers from lowering the artificially inflated WAC prices as explained in Paragraphs 74–118 and 174–186; (2) stifles the ability of less expensive drugs to enter the market (*e.g.*, biosimilars) as described in Paragraphs 74–118 and 174–186; and (3) many consumers are forced to purchase drugs with high WAC prices and pay higher out-of-pocket costs based on the artificially inflated WAC prices as described in Paragraphs 132–141.

Defendants' Pharmacy-Related Practices

250. For at least the last five years, Defendants have used their significant leverage to force independent pharmacies to accept unfair contract terms that materially disadvantage independent pharmacies and consumers as explained in Paragraphs 187–217. This includes Defendants forcing independent pharmacies to accept unfair reimbursement rates which are near or sometimes even below acquisition costs as explained in Paragraphs 192–202 and steering mail order and specialty business, which is significantly more profitable, to Defendants' affiliated pharmacies as explained in Paragraphs 203–217. These methods of competition are unfair because they go beyond competition on the merits.

251. Defendants' conduct is coercive, exploitative, collusive, abusive, deceptive, predatory, restrictive, and exclusionary because Defendants are taking advantage of their

significant power in the PBM market to force their competitors in the pharmacy market to accept unfair contractual terms as described in Paragraphs 187–217. Defendants' conduct also denies consumers free and fair access to the pharmacy of their choice as described in Paragraphs 187–217.

252. Defendants' conduct tends to negatively affect competitive conditions because it: (1) disadvantages independent pharmacies by reimbursing them at or near acquisition cost for many drugs while systematically blocking them from business with higher profit margins, reducing their ability to provide services to consumers and compete in the pharmacy market as described in Paragraphs 192–202; (2) significantly reduces and, in some instances, eliminates competition in the mail order and specialty pharmacy business by forcing consumers to use Defendants' affiliated pharmacies as described in Paragraphs 187–217; and (3) drives up costs for consumers, particularly with respect to specialty drugs as described in Paragraphs 211 and 215–217.

253. Upon information and belief, the Government believes Defendants' conduct is ongoing.

PRAYER FOR RELIEF

The Government of Puerto Rico prays for entry of judgment against Defendants individually, and jointly and severally, for all the relief requested herein and to which the Government may otherwise be entitled, including, without limitation, that the Court:

A. Enter an Order and Judgment against Defendants, and in favor of the Government, for each violation alleged in this Complaint;

B. Declare that Defendants' acts and practices alleged herein are unfair and deceptive practices and/or constitute unfair methods of competition in violation of 10 L.P.R.A.

§ 259; and that Defendants' conduct breached and violated the statutory causes of action alleged herein;

C. Enjoin Defendants from engaging in unfair and deceptive practices and unfair methods of competition in violation of 10 L.P.R.A. § 259.

D. Require Defendants to pay all consumer restitution that may be owed to Puerto Rico consumers affected by Defendants' unlawful acts and practices;

E. Require Defendants to disgorge ill-gotten gains;

F. Require Defendants to pay for the damages incurred by the Government as a result of Defendants' unfair and deceptive acts and practices pursuant to 10 L.P.R.A. § 268(b).

G. Given the repeated and ongoing violations of the law, punish violations of 10 L.P.R.A. § 259 by an Order requiring Defendants to pay maximum civil penalties under 10 L.P.R.A. § 269 for each and every violation of section 259;

H. Assess and award a judgment in favor of the Government and against Defendants for costs and pre- and post-judgment interest; and

I. Award any and all other relief this Court deems appropriate.

RESPECTFULLY SUBMITTED.

In San Juan, Puerto Rico, this 20th day of December, 2024.

DOMINGO EMANUELLI
SECRETARY OF JUSTICE
DEPARTMENT OF JUSTICE
OF PUERTO RICO

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EXHIBIT A

FEHB Program Carrier Letter
Experience-Rated HMO and Fee-For-Service Carriers

U.S. Office of Personnel Management
Healthcare and Insurance

Letter Number 2024-02

Date: January 25, 2024

FEHB [xx] PSHB [xx]

Fee-for-service [2] Experience-rated HMO [2] Community-rated HMO [n/a]

Subject: Pharmacy Benefits Management (PBM) Transparency Standards

This Carrier Letter clarifies Pharmacy Benefit Manager (PBM) Transparency Standards for fee-for-service (FFS) and experience-rated (ER) HMO Carriers.

In the event of a conflict between this letter and a prior FEHB Carrier Letter, this letter supersedes.

Background

OPM has included PBM standards in FEHB contracts since 2005 for FFS Carriers and 2008 for ER HMO Carriers. In 2011, new transparency standards were implemented for FFS Carriers, including requiring PBMs to base Carrier costs on negotiated price with network pharmacies or the actual acquisition cost for PBM-owned or affiliated pharmacies. Throughout the years, OPM has remained firmly committed to transparency standards regarding prescription drug benefits as an integral part of administering the FEHB Program. Due to the added layers of complexity related to PBMs' business practices over the years, OPM is reissuing this guidance.

These requirements regarding PBM transparency also apply to Medicare Employer Group Waiver Plans (EGWPs) offered to FEHB and PSHB enrollees and their family members.

PBM Transparency Oversight

FFS and ER HMO Carriers are required to adhere to the following principles to ensure appropriate oversight of PBMs.

- Carriers must have a robust set of mechanisms and processes, including detailed policies, audit standards, and terms to provide oversight of PBMs.
- Carriers must have full audit rights to all PBM network pharmacy contracts, claims data, manufacturer payments,[1] invoices, and clinical services coverage criteria.
- Carrier contracts with PBMs must not have terms which prohibit Carriers from determining who may conduct audits and frequency of audits.
- FFS and ER HMO Carriers with PBM contracts that are considered large provider agreements[2] must conduct audits of books and records directly related to drug payments and contract agreements at the contracting officer's discretion. Carriers must submit a summary of audit findings and corrective action plans, if applicable, to the contracting officer and copy OPMPharmacy@opm.gov starting no later than January 1, 2026.
- If the Carrier contracts with a third party to conduct an audit of a PBM, the Carrier must use independent auditors without conflicts of interest to conduct comprehensive audits.
- Carriers must have the authority to determine any terms involved in audits (except for the Federal Government audit entities audits), including contract compliance, pricing, financials, manufacturer payments, or other relevant details. This right would extend to any applicable subcontractors and vendors, including but not limited to rebate processors.
- Carriers must provide oversight of formulary management, including but not limited to any formulary changes involving hyperinflationary

[1] "Manufacturer payments" means any and all compensation, financial benefits, or remuneration the PBM or any third party receives from a pharmaceutical manufacturer for any dispensing or distribution channel, including but not limited to, discounts, credits, rebates (regardless of how categorized), market share incentives, chargebacks, commissions, administrative or management fees, patient assistance and any fees received for sales of utilization data to a pharmaceutical manufacturer.
[2] Federal Employees Health Benefits Acquisition Regulation: Large Provider Agreements, Subcontracts, and Miscellaneous Changes, 70 FR 31374 (2005).

concerns, mid-year changes, new-to-market drugs[3], brand drugs with generic equivalents available, and over-the-counter drugs.

- Contracts between PBMs and Carriers shall include clear details related to manufacturer payment schedules and fees generated from manufacturers.
- Carriers' transparency standards must include terms related to having access to information at each claim and aggregate level between PBMs and pharmacies (including PBMs and PBM-owned or affiliated pharmacies).
- Carrier contracts with PBMs must provide information related to all contractual terms, including but not limited to the clear definition of brand, generic, and specialty drugs, default discount guarantee for any new-to-market drugs, carve-out rights allowing the entity to obtain specialty drugs from other pharmacies, and drug-by-drug manufacturer payment for all drugs.
- PBM contracts must also clearly contain terms related to PBM-rebate aggregators, group purchasing organization arrangements, pricing methods for all pharmacy distribution channels (e.g., retail, mail, and specialty), refill protocols, meaningful performance guarantees, and network adequacy terms.
- All contracts, agreements, other documentation, or evidence related to the pharmacy benefit design and costs, including but not limited to invoices, receipts, and credits, that support amounts charged to the Carrier contract must be fully disclosed within 30 days of request without redaction to and must be auditable by the Carrier, OPM contracting officer, and the OPM OIG upon request.

Pass-Through Transparent Pricing[4]

FFS and ER HMO Carriers must ensure their PBMs adhere to the following transparent pricing standards. Additionally, Carriers must ensure that PBMs provide pass-through transparency for all pharmacy distribution channels. Pass-through transparent pricing standards do not apply to Medicare

[3] In this document, the term "drug(s)," it includes biological products. Biological products are regulated by the Food and Drug Administration (FDA) and are used to diagnose, prevent, treat, and cure diseases and medical conditions. Biological products are a diverse category of products and are generally large, complex molecules. *See* Biological Product Definitions, FDA.

[4] As defined in OPM's contracts with Carriers, "pass-through transparent pricing" means drug pricing in which the Carrier receives the full value of all discounts, rebates, credits or other financial guarantees or adjustments including any true up or reconciliation.

Prescription Drug Plans (PDPs) or Medicare Advantage Prescription Drug (MA-PD) plans where the PDP or MA-PD sponsor, with which the Carrier contracts, bears the risk.

- The cost of drugs, products, and supplies filled by pharmacies not affiliated with the PBM shall be based on the negotiated price in each pharmacy agreement and the pass-through transparent pricing at the value of the pharmacy agreement for each drug plus a dispensing fee.
- The cost of drugs, products, and supplies filled by PBMs-owned or affiliated pharmacies shall be based on the actual acquisition cost, plus a dispensing fee and pass-through transparent pricing.
- PBMs must disclose all Maximum Allowable Cost lists[5] used for Carriers' pricing and provide the rationale for having more than one list.
- Carriers must have access to plan-specific net drug cost information (after manufacturer payments, network pharmacy discounts, PBM negotiated discounts, and any other discounts from any other sources) at each drug code level.
- The PBM must agree to disclose each fee to the Carrier and OPM.
- A PBM's administrative fee shall represent the PBM's sole source of profit. Any additional fees collected by the PBM for retail pharmacy transactions must be credited back to the Carrier.
- PBMs shall not charge Carriers more than the value of the PBM's negotiated discounts with each pharmacy in effect at the time of claim adjudication. True-ups to any pricing guarantees should be performed quarterly.
- Except for the costs associated with dispensing the drugs, a PBM shall not create additional markups for 340B[6] claims.
- Carriers must ensure that members are charged the lesser of the prescription price or applicable cost-share amount for prescription

[5] Maximum Allowable Cost (MAC) pricing is a payment model contractually agreed to in the marketplace by all participants. The model ensures that those purchasing health insurance benefits, including individual consumers, do not overpay for generic drugs. MAC pricing is designed to promote competitive pricing for pharmacies as an incentive for them to purchase less costly generic drugs available in the market, regardless of the manufacturer's list price, since manufacturers will charge different amounts for equally interchangeable generic drugs. *See* Maximum Allowable Cost (MAC) Pricing, available at AMCP.org.

[6] The 340B Program allows certain hospitals to buy outpatient drugs at discounted prices. To be eligible for the program, hospitals generally must treat a minimum percentage of low-income Medicare and Medicaid patients. Rosenberg, Michelle B. (May 11, 2023), 340B Drug Discount Program*: Information about Hospitals That Received an Eligibility Exception as a Result of COVID-19*. U.S. Government Accountability Office.

drugs. OPM considers the prescription price to be the drug's negotiated price plus dispensing fee or the cash price at the point of sale.

- PBMs must report their Actual Acquisition Cost for PBM-owned or affiliated pharmacy drugs dispensed at each claim and aggregate levels within six months of the quarter in which manufacturer payment was earned.
- All administrative and dispensing fees must be clearly attributable to retail, mail, specialty claims, clinical programs, and any other programs.

Pass-Through Transparent Manufacturer Payments

- FFS and ER HMOs Carriers must ensure their PBMs adhere to the following manufacturer payment transparency standards. Again, pass-through transparent manufacturer payments standards do not apply to Medicare PDPs or MA-PDs where the PDP or MA-PD sponsor, with which the Carrier contracts, bears the risk. PBMs shall disclose to Carriers all contracts with drug manufacturers[7] and intermediary contracting organizations.
- PBMs must disclose to Carriers drug manufacturer payment information at each claim and at aggregate levels, all sources of revenue or other consideration, including all sources of manufacturer payments for each business segment for that contract year, and the attribution of administrative fees to claims and service.
- PBMs must pass through to Carriers one hundred percent (100%) of current, past, and future drug manufacturer payments in any form, regardless of whether the applicable benefit is billed as pharmacy or medical.
- PBMs shall pass through to Carriers one hundred percent (100%) of manufacturer payments, discounts, bulk purchase/volume incentives, commissions, credits, price concessions, or any other financial benefits received from drug wholesalers, rebate aggregators, and group purchasing organizations related to the cost of drugs filled by PBM-owned or affiliated pharmacies.
- Rebate aggregators or group purchasing organizations that are owned by or affiliated with the PBM are required to pass through to Carriers 100% of the manufacturer payments collected from drug manufacturers.

[7] Drug manufacturers do not include rebates aggregators, distributors, wholesalers, or other entities that do not manufacture drugs.

- Entities owned by or affiliated with the Carrier or PBM that manufacture, co-brand, co-license, commercialize and/or co-produce or distribute drugs are required to pass through 100% of the manufacturer payments to Carriers.
- PBMs must pass through to Carriers all drug inventory purchasing discounts associated for retail, mail order, and specialty drugs.
- Any credit that the PBM receives back from any pharmacies related to the processing of a Carrier's prescription drug benefits should be deducted from the cost of drugs since the administrative fees shall cover all administrative expenses as the sole source of profit.
- PBMs must pass to Carriers one hundred percent (100%) of fees received from a manufacturer for formulary placement or access.
- For any utilization management and educational programs/initiatives that PBMs implement, Carriers must require full disclosure of any resultant revenue and have policies in place to ensure Carriers' approval prior to implementation.

Additionally, Carriers should include mechanisms aimed at managing costs, such as requiring PBMs to perform market checks at least annually during the contract term. A contract between a Carrier and a PBM shall not exceed 3 years without re-competition unless the contracting officer approves an exception.

OPM will decline any arrangements which may manipulate the prescription drug benefit design or incorporate any programs such as copay maximizers, copay optimizers, or other similar programs as these types of benefit designs are not in the best interest of enrollees or the Government.

To provide effective and affordable prescription drug benefits, Carriers must exercise due diligence, implement these standards, and use transparent pass-through pricing and manufacturer payments when contracting with PBMs. Carriers are required to apply the transparency standards mentioned above with current PBM contractors and subcontractors.

Conclusion

OPM remains committed to the highest PBM transparency standards in administering the FEHB Program and requires review and incorporation of these standards in PBM contracting arrangements.

For questions about this Carrier Letter, please contact OPMPharmacy@opm.gov and copy your contracting officer.

Sincerely,

Laurie Bodenheimer
Associate Director
Healthcare and Insurance